DIS 9001 2014

UNDERSTANDING THE DRAFT INTERNATIONAL STANDARD

IRCA
INTERNATIONAL REGISTER OF CERTIFICATED AUDITORS

CQI
Chartered Quality Institute

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Introduction

Every year for the past 20 years, the International Organization for Standardization (ISO) has conducted a survey that is designed to provide an insight into the worldwide adoption of ISO's management system standards.

The latest edition (2013) reveals a healthy growth across the board for all management system standards as at the end of 2012, with a total of 1.5 million certifications globally. Of these, 1.1 million were against ISO 9001, exceeding the total issued against all other ISO management system standards combined by a factor of 3 to 1. Accordingly, any revision of ISO 9001 will have global implications based simply on numbers alone. The 2015 release, however, is set to be particularly significant as a result of fundamental changes to both its structure and its contents. Complying with the revised requirements will present new challenges for quality and audit professionals alike.

By raising awareness now, organisations and individuals can begin to develop their migration strategies.

Purpose of this report

This report examines the current contents of the Draft International Standard (DIS 9001:2014), translating each clause into 'plain English' before moving on to consider the implications of the clause from the perspective of those entrusted with overseeing the operation of their quality management systems and those engaged in the audit of quality management systems.

It is intended to assist both Chartered Quality Institute (CQI) and International Register of Certificated Auditors (IRCA) members in preparing for the new standard – preparation that can and should begin now. While standards can and do evolve between their DIS and their final release version, what we already know for certain is that those changes arising as a result of the adoption of Annex SL (previously known as ISO Guide 83) are going to be incorporated into ISO 9001:2015, and it is these changes that we believe will have the most significant impact for both quality and audit professionals.

By raising awareness now, organisations and individuals can begin to develop their migration strategies.

What happens next?

The ISO 9001:2015 DIS was published on 14 May 2014. From this date through to 12 October 2014, those based in the United Kingdom will be able to register their comments on the DIS using the BSI Draft Review System (http://drafts.bsigroup.com/).

For those located outside of the UK, each country's National Standards Body will have its own arrangements in place to allow individuals to record their views on the contents of the DIS.

In addition, the CQI has been awarded Category A liaison status to TC 176, the Technical Committee responsible for developing the new standard. This special recognition permits the CQI to provide a collective response on the DIS directly to TC 176 on behalf of all of its members. In order to inform this response, the CQI will survey its members during July 2014.

> Life should become easier for management system standard writers.

Whichever way you choose to provide feedback, the CQI and IRCA would urge you to express your opinion. The DIS ballot phase provides the last real opportunity for customers of the standard to have a material input into how ISO 9001:2015 will ultimately appear. History suggests that the next major revision of the standard will be sometime between 2025 and 2030; therefore, if there are concerns over the current contents of the DIS, it is essential that these are identified and addressed before the standard development process moves on to the next phase.

When the DIS ballot window closes in October 2014, all of the comments received worldwide will be analysed. Those that are accepted will be worked into the Final Draft International Standard (FDIS 9001:2015), which we are expecting to see in July 2015. At this point, the standard will be substantively complete and only minor editorial changes can be considered.

The International Standard itself, ISO 9001:2015, is scheduled for publication in September 2015.

Executive summary

The CQI has direct access to TC 176, the Technical Committee responsible for updating the current version of the standard, ISO 9001:2008. As such, we have a specific insight into not only the content of the new version but also the intention behind the content.

There has been some debate internationally about the implications of the proposed changes for both quality and audit professionals. Some national bodies regard the changes as insignificant, taking the view that ISO 9001:2015 simply introduces a number of requirements that were previously implied in ISO 9001:2008 but that were not mandated.

The CQI and IRCA do not share this position. We remain convinced that those leading, managing and auditing quality management systems will need to revise their current thinking and work in different ways in order to maintain organisational compliance.

What has led us to this conclusion?

The changes incorporated into DIS 9001:2014 can essentially be divided into those that have arisen as a result of the adoption of Annex SL as the basis for the standard and those that have arisen as a result of the desire to amend current quality management specific requirements.

In the preface to IRCA briefing note: Annex SL (available free of charge on both the CQI and IRCA websites), we describe the introduction of Annex SL as "the most important event since ISO 9001". Its adoption has implications for all those using management system standards, be they standard writers, management system implementers, auditors or training providers.

Life should become easier for management system standard writers. They can now concentrate their efforts on developing the discipline-specific requirements that will be focused on Clause 8 – Operation. Will this lead to shorter development times for ISO standards? Hopefully yes, but we will need to wait to see if this proves to be the case in practice.

Implementers of management systems should find life easier too. Those seeking to introduce multiple management systems (eg Quality, Environmental, Health and Safety) will have less work to do because in future, the core requirements of these will be identical. This will simplify both the initial implementation and the ongoing maintenance of such systems.

For management system auditors, the adoption of Annex SL means that there will be a generic set of requirements that need to be assessed when conducting management system audits, irrespective of the discipline that is being audited.

As a result of the above, we expect to see training organisations start to offer generic management system auditing courses as alternatives to their currently offered discipline-specific ones. Those auditors wishing to achieve sector-specific registration would then complete secondary modules to top up their earlier generic training.

IRCA has already advised IRCA-Approved Training Organisations to adopt such an approach when designing auditor transition training courses, and is committed to reviewing its core Foundation, Internal Auditor, Auditor/Lead Auditor and Auditor Conversion courses later this year.

While the adoption of Annex SL will ultimately benefit all those who make active use of management system standards, in the short term there will be challenges for those concerned with establishing, implementing, managing or auditing against ISO 9001.

The impact is likely to be greatest for practitioners and auditors rather than the organisation itself, as many of the new and enhanced requirements are things that organisations and businesses should be doing already – for example, understanding the needs and expectations of stakeholders.

The difference will be that these activities will have to be transparent and demonstrable, so organisations may need to make some activities more evident than they currently are.

For those organisations already living by the spirit of ISO 9001:2008, the transition to ISO 9001:2015 should prove relatively straightforward. Whereas, for those organisations that are simply complying with the requirements of ISO 9001:2008 at the most basic level, work will be required to address the current culture of the organisation.

Culture can be described as "the way things are done around here" – however, this culture will have to change as a consequence of the adoption of Annex SL as the basis for ISO 9001:2015. This includes the behaviours of everyone connected with the quality management system, and, in particular, of those operating at the most senior level within an organisation.

Culture change can be notoriously difficult to effect and it is primarily for this reason that the CQI and IRCA have taken the position that ISO 9001:2015 represents such a significant revision.

ISO 9001:2015 will now make us do the things ISO 9001:2008 always wanted us to do but did not specify due to resistance from some parties.

Summary of principal changes – ISO 9001:2008 to ISO 9001:2015

- The new draft standard adopts the high-level structure and terminology of Annex SL. Annex SL was developed to ensure all future ISO management system standards would share a common format, irrespective of the specific discipline to which they relate. Annex SL prescribes a high-level structure, identical core text, and common terms and definitions. This means that even when requirements are essentially unchanged between ISO 9001:2008 and DIS 9001:2014, these are frequently found under a new clause/sub-clause heading.

- Clause 5, previously "Management Responsibility", now becomes "Leadership". Top management are required to demonstrate that they engage in key quality management system activities as opposed to simply ensuring that these activities occur. This means that there is a need for top management to be actively involved in the operation of their quality management system. The removal of all references to the role of "management representative" reinforces a desire to see quality management systems embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.

- Two new clauses (4.1 and 4.2) are introduced relating to the context of the organisation. Organisations will be required to identify explicitly any internal and external issues that may impact their quality management system's ability to deliver its intended results. They must also understand the needs and expectations of "interested parties" – those individuals and organisations that can affect, be affected by, or perceive themselves to be affected by, the organisation's decisions or activities.

- DIS 9001:2014 places a greater emphasis on the definition of scope of the quality management system than ISO 9001:2008 does. Scope sets the boundaries for, and identifies the applicability of, an organisation's quality management system. Clause 4.3 requires scope to be determined in consideration of the organisation's context.

- While ISO 9001:2008 promoted the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, clause 4.4 of DIS 9001:2014 sets out specific requirements designed to enforce its adoption.

- References to preventive action have disappeared – however, the core concept of identifying and addressing potential mistakes before they happen very much remains. DIS 9001:2014 now talks in terms of risk and opportunities. Organisations must evidence that they have determined, considered and, where necessary, taken action to address any risks or opportunities that may impact (either positively or negatively) their quality management system's ability to deliver its intended outcomes or that could impact customer satisfaction.

- The term "product" will be replaced by "products and services". Previously, the inclusion of services as products was implicit. By including explicit reference to services, the standard writers are attempting to reinforce that 9001 is applicable to all suppliers, not just those that provide physical products.

- DIS 9001:2014 clause 10 recognises that incremental (continuous) improvement is not the only improvement profile. Improvement can also arise as a result of periodic breakthroughs, reactive change or as a result of reorganisation. Thus, the title of this clause is now "Improvement" (ISO 9001:2008 8.5.1 referred to "Continual improvement").

- The phrase "externally provided products and services" replaces "Purchasing". Clause 8.4 addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organisation, or by any other means. Organisations are required to take a risk-based approach to determine the type and extent of controls appropriate to each external provider and all external provision of products and services.

- References to a documented quality manual, documented procedures and to quality records have been removed. Instead, throughout DIS 9001:2014 there are specific references to "Documented Information". This is information that the organisation is required to keep, control and maintain. How it wishes to record this information is up to the organisation itself; formats and storage methods are not prescribed in the DIS.

- There has been a conscious attempt to revisit the wording of the standard with a view to making the requirements easier to understand and to aid its translation.

- Where requirements were previously implied, the wording of the standard has been amended to make them explicit. Understanding the organisation and its context, and the adoption of a process-based approach, are perhaps the most significant examples but these are not the only instances, as a detailed examination of the clauses confirms.

- Terms and definitions have now been brought into the body of DIS 9001:2014. ISO 9001:2008's terms and definitions reside in a separate standard, ISO 9000:2005. However, for DIS 9001:2014, terms and definitions are contained within the requirements standard itself. This has significantly increased the size of the DIS and will consequently also impact its pricing.

- DIS 9001:2014 has three informative annexes. Annex A provides clarification on the new structure, terminology and concepts underpinning the DIS, while Annex B provides refreshed Quality Management Principles, which are drawn across from ISO 9004. Annex C details related quality management system standards from ISO's 10000 series. These are designed to provide assistance to organisations seeking to establish or improve their quality management performance.

Key changes you do not need to make

Organisations do not need to:

- Remove their management representatives. While there is no requirement in DIS 9001:2014 for a management representative, this does not prevent organisations from choosing to retain this role if they so wish. Be aware, however, that some of the duties traditionally assigned to the management representative by top management will, in future, need to be undertaken directly by top management themselves.
- Throw out their Quality Manuals and Documented Procedures. While DIS 9001:2014 sets out no requirement for organisations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn.
- Renumber existing QMS documentation to correspond to the new clause references. Although organisations may choose to carry out a renumbering exercise, it is down to each to determine whether the benefits gained from renumbering will exceed the effort involved in actioning the change. However, reference needs to be made to compliance with 9001:2015, if the organisation wishes to demonstrate compliance to this standard.
- Restructure their management systems to follow the sequence of requirements as set out in the DIS. Providing all of the requirements contained in the DIS are met, the organisation's system will be compliant.
- Refresh existing documentation to use the new terms and definitions contained within DIS 9001:2014. Once again, organisations are free to make the judgement as to whether this effort would be worthwhile. If organisations are more comfortable using their own terminology, eg "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.

> There has been a conscious attempt to revisit the wording of the standard with a view to making the requirements easier to understand.

Interpretation

The interpretations of requirements contained within this document are those of the CQI/IRCA – other organisations may interpret the requirements of DIS 9001:2014 differently.

As such, this document should not be viewed as the definitive reference source for this draft international standard; indeed, there is no document that can fulfil this purpose.

Clause by clause evaluation

This next section of the report sets out to:

- simplify the requirements of each clause of DIS 9001:2014 into language that is easier to understand;
- identify whether each requirement is a new requirement or an amended version of an existing ISO 9001:2008 requirement;
- identify the implications of the requirement for quality professionals (quality managers, quality directors, system implementers);
- identify the implications of the requirement for audit professionals.

Note: neither the CQI nor the IRCA are permitted to reproduce the exact wording of the standard due to copyright restrictions. Those individuals who need access to the exact wording should make their own arrangements to source the standard from a legitimate supplier.

Clause by clause evaluation

While there have been only minor changes to the wording of the Foreword for DIS 9001:2014, the most significant point to note in this section are statements in the respective standards that set in context the magnitude of the change we are about to experience in moving from ISO 9001:2008 and DIS 9001:2014.

- ISO 9001:2008 was issued "to clarify points" in the text of ISO 9001:2000 and to "enhance its compatibility with ISO 14001:2004".
- DIS 9001:2014, however, is a "technical revision, introducing a new structure, new quality management principles and new concepts".

The detail of this report reinforces the fact that this is a major upgrade to the current version of ISO 9001; indeed, it is arguably the greatest revision since the standard was first published in 1987.

ISO 9001:2015 DIS

Introduction

0.1 General

ISO 9001:2008 reminds us that that the adoption of a quality management system is a strategic decision for the organisation. It is not something an organisation is compelled to do.

Similarly, it acknowledges that the design and implementation of the quality management system will be in part dependent on:

- the organisation's context and its specific objectives;
- risks associated with its context or specific objectives;
- the products and/or services it is seeking to provide;
- the complexity of its processes;
- its size and organisational structure.

DIS 9001:2014 adds two further considerations to this list – the needs and expectations of the organisation's customers and relevant interested parties, and the competency of persons within, or working on behalf of, the organisation.

We are reminded that the standard does not prescribe how the organisation's quality management system should look. Instead, the organisation can address the requirements in the way that suits them best.

We are also reminded that the standard may be used by both internal and external parties as the basis for assessment.

Note: ISO 9001:2008 refers to the organisational environment, changes in that environment and risks associated with that environment. DIS 9001:2014 expands the concept of the organisational environment to include not only the business environment, but also internal factors, such as organisational culture, and external factors, such as socio-economic conditions under which it operates. DIS 9001:2014 replaces "organisational environment" with "context of the organisation".

0.2 The ISO standards for quality management

This is a new sub-clause for DIS 9001:2014. It confirms that there are three core quality management system standards: 9000, 9001 and 9004. An overview is provided for each.

We are then directed to Annex C for a list of other guidance standards developed to support the implementation of a quality management system comprising the ISO 10000 series.

> DIS 9001:2014 acknowledges that risk-based thinking has always been implicit in 9001.

0.3 Process approach

Although ISO 9001:2008 stated that it promoted the adoption of a process approach, this was more of an encouragement than a requirement. However, with the introduction of DIS 9001:2014, there is now no choice in the matter, with requirements around process appearing throughout the standard and the process approach being referred to as "essential" in this section.

The diagram introduced into ISO 9001:2008 depicting a "model of a process-based quality management system" has been extensively revised and now references the clause numbers used in the DIS. Box titles have also been changed to reflect the new terminology (eg "Leadership" replaces "Management responsibility", "Planning" replaces "Resource management", etc) and "Support Processes" has been added, underpinning the operation of the whole QMS. Also added is a two-way exchange between "Context" and "Customers" and other relevant, interested parties.

0.4 Plan-Do-Check-Act cycle

When CD 9001:2015 was published without the familiar "Plan-Do-Check-Act" (PDCA) cycle diagram, some questioned whether the PDCA approach had been removed from the standard. This section confirms PDCA is very much alive and operating at both a process level and an overall system level too. A second diagram to show a process has been added.

0.5 "Risk-based thinking"

DIS 9001:2014 acknowledges that risk-based thinking has always been implicit in 9001. However, as is the case regarding the process approach, the DIS makes the requirement for risk-based thinking explicit at certain points throughout the standard. The DIS does not prescribe a risk methodology that the organisation must adopt; instead, each organisation is free to decide its own approach. The robustness of the risk approach must be proportionate to the consequences, should the risk be realised.

0.6 Compatibility with other management system standards

The DIS 9001:2014 confirms the adoption of Annex SL, which has been introduced to ensure a level of consistency across all management system standards. It points to Annex A of DIS 9001:2014 where some of the key changes introduced in this version of the standard are detailed.

Users of the standard are reminded that they do not need to follow a clause structure that mirrors Annex SL when establishing or refreshing their own systems.

Finally, there is a reminder that, although DIS 9001:2014 does not include any requirements specific to other management systems (eg environmental management, health and safety management or asset management), there is nothing to stop organisations integrating such systems with their quality management system should they wish to do so. Annex SL should make this process easier.

1 SCOPE

The overall purpose of the standard is unchanged from ISO 9001:2008. It is still intended as a means by which organisations can demonstrate their ability to supply products and services that consistently meet customer and applicable statutory and regulatory requirements. It is also for use where an organisation is seeking to enhance its customers' satisfaction as a result of it operating a quality management system.

All references to "exclusions" in ISO 9001:2008 sub-clause 1.2 "Application" have been removed. This is because all of the requirements in ISO 9001:2015 are intended to be applicable to all types and size of organisation.

However, DIS 9001:2014 Annex A A.5 recognises that there may be circumstances where it is impossible for an organisation to conform to a specific requirement – for example, where it does not operate a "required" process. In these instances, the organisation can deem the requirement "not applicable" providing this does not affect its ability to supply conforming products or services, or compromise its aim to enhance customer satisfaction.

Within Note 1, the ISO 9001:2008 reference to "output resulting from product realisation" has been removed.

2 NORMATIVE REFERENCES

ISO 9001:2008 cited ISO 9000:2005 quality management systems – fundamentals and vocabulary as a normative reference. This means that these two documents were intended to be used as a pair.

As a result of the incorporation of content previously contained within ISO 9000:2005 directly into DIS 9001:2014, the need for DIS 9001:2014 holders also to acquire ISO 9000:2005 has been removed.

Consequently DIS 9001:2014 now contains no normative references.

3 TERMS AND DEFINITIONS

The terms and definitions for ISO 9001:2008 were contained within a supplementary standard, ISO 9000.

For DIS 9001:2014, these have been brought directly into the primary standard. While this ensures that they are readily available, it has effectively doubled the size of DIS 9001:2014 when compared to ISO 9001:2008. As ISO prices standards on a 'per-page' basis, this could have a significant impact on its cost.

Note that some of the current definitions have changed, that there are some terms which were not defined in 9000:2005 (eg monitoring, performance) that are now defined in DIS 9001:2014, and that there are definitions for some of the new terms used in 9001:2015 (eg risk, innovation)

4 CONTEXT OF THE ORGANIZATION

4.1 Understanding the organization and its context

► INTERPRETATION:

DIS 9001:2014 requires organisations to identify, monitor and review internal and external issues that are relevant to its purpose and strategic direction, and that have the ability to impact the quality management system's intended results.

IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is the first of two new clauses introduced into DIS 9001:2014 relating to "Context".

Most organisations will already be successfully monitoring internal and external issues that have the potential to affect not only their quality management system, but also the very existence of the organisation itself. They will now need to evidence this process to their auditors.

IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors will need to allow additional time to prepare for audits in order to establish their understanding of the context that auditee organisations are operating in. They will need to understand the internal and external issues typically experienced in organisations of that type, and must be prepared and able to challenge an organisation if they believe the organisation's interpretation of their context is deficient or incorrect.

Evidence needs to be obtained to provide assurance that organisations are reviewing internal and external issues at periodic intervals.

4.2 Understanding the needs and expectations of interested parties

► INTERPRETATION:

The organisation is required to determine "the relevant requirements" of "relevant interested parties".

Once determined, the organisation must then monitor and review the information it holds about these parties and their requirements.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is another new clause introduced for DIS 9001:2014.

"Relevant interested parties" are groups or individuals who have the ability to impact (or potentially impact) the organisation's ability to supply consistently products and services that meet customer and applicable statutory and regulatory requirements. Customers, shareholders, board members and competitors would all fit into this classification. Each organisation will have its own set of relevant interested parties and this set will change over time.

Very few of the relevant interested parties' total requirements will be relevant to the operation of a particular organisation's quality management system. These very few are the ones that the organisation needs to capture.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

As for clause 4.1 above, auditors will need additional time to prepare for audits in order to establish their view of the relevant interests of relevant interested parties. If this differs from the organisation's perception, then auditors must be prepared to challenge this.

Auditors will need to ensure that the organisation has been through a process initially to identify these groups and then to identify their requirements that are relevant to the organisation's quality management system.

They will also need to ensure that this process is revisited periodically because the relevant requirements of relevant interested parties may change over time.

> DIS 9001:2014 requires the organisation to establish a process-based quality management system.

4.3 Determining the scope of the quality management system

▶ INTERPRETATION:

The scope of a quality management system sets its boundaries, identifying what the requirements of the quality management system are applicable to, and to what they are not.

The scope of the quality management system is defined by the organisation.

When defining the scope of its quality management system, the organisation needs to take into account its context (eg the internal and external issues it faces and the requirements of relevant interested parties), and also the products and/or services it intends to deliver.

The scope must be made available and be maintained as documented information.

The scope needs to state the products and services covered by the quality management system and must also include any justifications or instances where specific elements of DIS 9001:2014 cannot be applied (for example, where a required process is not undertaken).

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The organisation has always been required to specify the scope of its quality management system. However, this must now be done in explicit consideration of the organisation's context, as well as in terms of the products and services it intends to supply.

DIS 9001:2014 makes it clear that if a requirement of the standard can be applied, given the organisation's determined scope, then it must be included. Only in cases where meeting the requirement is impossible (and where the absence of meeting the requirement does not adversely impact the organisation's ability to supply conforming products and services) is it permissible not to apply it.

This replaces "exclusions", which are referenced in ISO 9001:2008 clause 1.2 (Application). which acknowledges that there may be instances where it is impossible to apply a specific requirement, but limits these to requirements appearing in clause 7 "Product realisation".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors will need to verify that the organisation's scope exists as documented information. They must gather evidence that it has been produced in consideration of the organisation's context and products and services.

Auditors should review any exclusions applied under ISO 9001:2008 for ongoing suitability. They will need to ensure legacy issues, where an organisation has previously sought to limit its scope and excluded activities that can affect its ability or responsibility to ensure conformity of products or services, are not perpetuated.

If exclusions have been applied by the organisation, auditors must ensure that they are recorded and that the rationale for the exclusion is stated and justified.

4.4 Quality management system and its processes

▶ INTERPRETATION:

DIS 9001:2014 requires the organisation to establish a process-based quality management system. Once in place this needs to be maintained and continually improved. Clause 4.4 sets out high-level requirements for the design of a process-based management system.

Most of what is given in clause 4.4 can be found in ISO 9001:2008, where the requirements are less clear and are fragmented across a number of clauses, including "General requirements" (clauses 4.1 and 8.1) and "Monitoring and measurement of processes" (sub-clause 8.2.3).

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The principal change from ISO 9001:2008 is an elevated focus on processes, which is something that appears throughout the DIS. Whereas ISO 9001:2008 "promoted" the adoption of a process approach, DIS 9001:2014 mandates this.

In addition, organisations need to determine performance indicators that allow for the effective operation and control of processes, determine responsibilities and authorities for processes, identify risks and opportunities for processes, and plan to address these.

The 9001:2008 requirement to determine opportunities to continually improve processes has been expanded to include "continually improve processes and the quality management system".

Organisations are required to maintain the documented information necessary to support the operation of its processes. They must also retain documented information that evidences that processes are being carried out as planned.

For organisations already applying ISO 9001:2008, the key factor(s) in meeting these requirements will be the extent to which the process approach has truly been embraced and adopted already. This includes the effectiveness of quality management system planning carried out under ISO 9001:2008 sub-clause 5.4.2, the effectiveness of planning of processes needed for product realisation carried out under ISO 9001:2008 clause 7.1, and the effectiveness of process monitoring, measurement, analysis and improvement carried out under ISO 9001:2008 sub-clause 8.2.3. For management system implementers, these will be key areas for review.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Audit professionals must note the explicit requirement for a process-based quality management system. This is now mandatory. They should also note the additional new requirements regarding use of performance indicators to control and monitor processes, and the requirement for processes to be assessed from a risk and opportunity perspective.

Clause 4.4 states explicit requirements that need to be met in the design, operation and maintenance of a process-based management system. For example, determination of inputs required and outputs expected, resources needed, and assignment of responsibilities and authorities. Although not strictly new requirements, DIS 9001:2014 makes it clear that these requirements are essential elements of a process-based management system that auditors will need to verify have been determined and implemented as required. In effect, auditors will need to review how the organisation has designed its process-based management system.

Existing operational procedures, work instructions and flow charts are valid examples of documented information and can be used to evidence that the requirement for documented information to support the operation of processes is being met. If these are working well for the organisation then there is no need to replace them.

> Auditors will need to review how the organisation has designed its process-based management system.

> They must drive continual improvement and innovation, and develop leadership in their managers.

5 LEADERSHIP

5.1 Leadership and commitment

5.1.1 Leadership and commitment to the quality management system

▶ INTERPRETATION:

DIS 9001:2014 replaces "Management responsibility" with "Leadership", and repositions a number of ISO 9001:2008 requirements as leadership activities.

Sub-clause 5.1.1 identifies specific aspects of the quality management system where top management are expected to demonstrate both leadership and commitment.

This starts with their taking accountability for the effectiveness of their organisation's quality management system. They must ensure that their organisation's quality policy and quality objectives are consistent with the organisation's overall strategic direction and the context in which the organisation is operating. They must also work alongside their people in order to ensure that the quality objectives are achieved. In addition, top management must ensure that the quality policy is communicated, understood and applied across the organisation.

Top management must also ensure that quality management system requirements are integral to the organisation's business processes – that is, the quality management system must not be just a "bolt on". They must promote awareness and the adoption of the "process approach", and must make sure that the resources required for the effective operation of the quality management system are made available.

Top management must stress the importance of effective quality management and of conforming to the requirements of the quality management system. They must make sure that the quality management system is achieving the results intended and must lead people to contribute to the effective operation of the system. They must drive continual improvement and innovation, and develop leadership in their managers.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The move from management commitment to "Leadership" and commitment is perhaps the most significant and far-reaching change contained within DIS 9001:2014, although the actual impact will depend very much on where each organisation is starting from.

For those where the most senior members of the organisation currently play an active role in driving its quality management system forward, the changes will simply be a formalisation of what is happening now. However, for those organisations where top management have effectively devolved responsibility for their quality management system to their Management Representative, the ramifications of the DIS 9001:2014 changes will be significantly greater.

ISO 9001:2015 requires top management to be much more "hands on" with respect to their quality management systems than ISO 9001:2008 does. Where the word "ensuring" is used in sub-clause 5.1.1, top management may still assign this task to others for completion. Where the words "promoting", "taking", "engaging" or "supporting" appear, these activities cannot be delegated and must be undertaken by top management themselves. Implementers will need to make top management aware of the new requirements, and the fact that they will now be audited as a matter of routine.

Note: when DIS 9001:2014 uses the term "top management", it is referring to a person or a group of people at the highest level within an organisation, ie the people who coordinate, direct, and control the organisation.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors must seek evidence that top management has a "hands-on" approach to the management of their quality management system.

Auditors must understand which DIS 9001:2014 requirements top management can delegate and which they cannot.

Auditors must ensure that they are equipped to challenge top management in respect of their commitment to their quality management systems. Auditing at this level is likely to be a new experience for many. To be effective and gain the respect of top management, auditors will need to have a good understanding of management activities, be able to engage with top management on a range of subjects, and speak the language of top management. For many auditors, this will involve developing new and enhanced competencies.

5.1.2 Customer focus

▶ INTERPRETATION:

Sub-clause 5.1.2 requires top management to take the lead in demonstrating the organisation's commitment to its customers.

They must ensure that customer and applicable statutory and regulatory requirements are identified and met. They must consider and address any risks that threaten the ability of the organisation to provide conforming products and/or services, or which may negatively impact customer satisfaction.

In addition, top management must also ensure the organisation remains focused on delivering conforming products and services, on meeting its statutory and regulatory obligations, and on enhancing its customers' satisfaction.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Sub-clause 5.1.2 expands on ISO 9001:2008 clause 5.2 by requiring top management now to ensure that risks and opportunities that could affect the organisation's ability to supply conforming products and services, and to enhance customer satisfaction, are identified and addressed.

The requirement to determine customer and applicable statutory and regulatory requirements is moved to this clause from ISO 9001:2008 sub-clause 7.2.1c.

Top management are now explicitly required to "maintain" a focus on consistently providing products and services that conform to customer requirements and that meet applicable statutory and regulatory requirements, as well as maintaining a focus on enhancing customer satisfaction.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors will need to seek evidence that top management are ensuring that any risks and opportunities with the potential to impact the organisation's ability to supply products and services that conform to customer requirements and applicable statutory or regulatory requirements, or that may affect customer satisfaction, are being identified and addressed by the organisation. Auditors should expect to find a focus on risks, but should note that opportunities must also be considered too.

Note: the requirement is to "maintain" a customer focus – this is, therefore, not a one-off exercise, but rather an activity that must be evidenced as ongoing.

5.2 Quality policy

▶ INTERPRETATION:

5.2.1

Sub-clause 5.2.1 sets out the requirements of top management in respect of the organisation's quality policy.

Top management must establish a quality policy that is consistent with the purpose and context of the organisation. It must additionally provide a framework for the setting and review of quality objectives, and include commitments to satisfy any applicable requirements and continually to improve their quality management system.

It is the responsibility of top management to review and maintain the quality policy.

▶ IMPLICATIONS FOR QUALITY PRACTITIONERS:

ISO 9001:2008 requires top management to "establish" the quality policy (5.1), and to "ensure" that it is reviewed for continuing suitability. DIS 9001:2014 requires that the top management "establish, review and maintain" a quality policy.

DIS 9001:2014 requires that the quality policy is also appropriate to the context of the organisation, not just its purpose. This will require the review of the organisation's quality policy after having decided on the context of the organisation and having considered the relevant requirements of the relevant interested parties.

The policy must include a commitment to continually improve the QMS. ISO 9001:2008 required a commitment to continual improve the effectiveness of the QMS.

The policy must now provide a framework for the setting and reviewing of quality objectives.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should seek evidence that top management have participated in the creation of the quality policy, and are reviewing and maintaining it. Auditors should ensure that the policy is appropriate to the context of the organisation as well as its purpose and that there is a commitment to improve the organisation's quality management system. They should also seek evidence that the organisation's quality objectives are consistent with the policy.

The requirement to determine that the quality policy is appropriate to the purpose and context of the organisation reinforces the need for auditors to establish their personal understanding of the context that the auditee organisation is operating in. However, from an audit perspective it is important that top management can demonstrate that the policy is compatible with the strategic direction and context of the organisation, as required by sub-clause 5.1.1b.

5.2.2

▶ INTERPRETATION:

Sub-clause 5.2.2 sets out specific requirements in respect of the organisation's quality policy. The policy must be available as documented information. It must be communicated, understood and applied across the organisation and must be available to relevant interested parties as appropriate.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

As an item of documented information, the quality policy can now be held in any manner that meets the requirements of DIS 9001:2014 clause 7.5.

Quality professionals should note that there is now an explicit requirement for the quality policy to be applied throughout the organisation. This can have some implications for implementers of the QMS.

The new requirement for the quality policy to be available to relevant interested parties, as appropriate, means that some organisations will need to demonstrate how this is done if they are not already making the policy available.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note that the ISO 9001:2008 requirement for "documented statements of quality policy and quality objectives" has now been removed. Instead, DIS 9001:2014 requires the policy to be maintained as documented information.

Auditors should ensure that the quality policy is being applied throughout the organisation and that the organisation is making the policy available to relevant interested parties where it is appropriate to do so.

> Quality objectives must be measurable, taking into account applicable customer and statutory and regulatory requirements.

5.3 Organizational roles, responsibilities and authorities

▶ INTERPRETATION:

This is largely a clarification of requirements given in clause 5.5 of ISO 9001:2008. The top management of the organisation need to ensure assignment of the necessary responsibilities and authorities to individuals within the organisation to carry out quality-related activities.

Specifically, they need to assign responsibility and authority for ensuring that:

- the requirements set out in DIS 9001:2014 are met;
- quality management system processes are delivering their intended outcomes;
- reporting on the operation of the quality management system and identifying any opportunities for improvement is taking place;
- a customer focus is promoted throughout the organisation;
- whenever changes to the quality management system are planned and implemented, the integrity of the system is maintained.

Top management need to ensure that responsibilities and authorities relating to an organisation's quality management system are communicated within the organisation and that they are understood within the organisation.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

DIS 9001:2015 requires that not only are responsibilities and authorities assigned, but that they are also communicated and understood within the organisation. The role of Management Representative has disappeared in DIS 9001:2014. This is an attempt to ensure that ownership of the quality management system does not centre around a single individual. Duties assigned to the Management Representative in ISO 9001:2008, including ensuring QMS processes are established and maintained, the reporting of QMS performance and promotion of customer requirements across the organisation, can now be assigned to any role or split across several roles.

Note: there is a new requirement for top management to ensure that someone is tasked with preserving the integrity of the quality management system while it is in the process of revision.

The quality professionals within the organisation may have to revisit the existing responsibilities and authorities with regards to the QMS, especially the responsibilities of top management. The review may identify gaps, including gaps of knowledge and skills, which will then need to be addressed before a compliant system can be established.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors must seek evidence that an organisation's people have not only been advised of their quality management system responsibilities and authorities, but that they also understand these in the context of what the quality management system is trying to achieve.

Auditors should note that there is no longer a requirement for an organisation to have an identified Management Representative, though the duties currently assigned to the Management Representative in ISO 9001:2008 must still be undertaken.

Auditors must seek evidence that top management have assigned responsibility and authority for preserving the integrity of the organisation's QMS during revisions or updates.

DIS 9001:2014 gives organisations and auditors opportunity to re-evaluate the effective assignment and communication of authority, as well as responsibility; authority often being vague and unclear.

6 PLANNING FOR THE QUALITY MANAGEMENT SYSTEM

6.1 Actions to address risks and opportunities

6.1.1

▶ INTERPRETATION:

Sub-clause 6.1.1 is a new requirement – organisations are required to consider their context when planning for their quality management systems. This means thinking about the internal and external issues they face and the relevant requirements of their relevant interested parties, and how this may impact on their quality management system design.

The organisation must then move on to determine the risks and opportunities that need to be addressed within its given context. This is in order to provide assurance that the quality management system can achieve its intended outcomes, to prevent or reduce undesired effects, and to achieve continual improvement.

> Risk management as an activity must now be carried out.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This sub-clause introduces a new requirement for organisations to determine those risks and opportunities that have the potential to impact the operation and performance of their quality management system, both positively and negatively.

While no specific risk-management methodology is prescribed, risk management as an activity must now be carried out.

Note: that 'risk' is specifically defined (Terms and Definitions 3.09).

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should seek evidence that confirms that an organisation has a methodology in place that enables them to effectively identify risks and opportunities in respect of the planning of their quality management system.

The role of the auditor is not to carry out their own determination of risks and opportunities, but to ensure that the organisation is applying their methodology consistently and effectively. However, where the auditor's knowledge of the context of the organisation reveals that the organisation has failed to identify a familiar known risk or opportunity, they may call into question the organisation's approach.

6.1.2

▶ INTERPRETATION:

Once the organisation has identified the risks and opportunities it faces, it must then determine how it wishes to address these.

There is a statement regarding proportionality to the effect that actions taken to address risks and opportunities should be in line with the potential impact of the risk or opportunity on the conformity of products and/or services, as well as on customer satisfaction. The associated note sets out potential strategies for mitigating risks, and recognises that not all risks and opportunities need actions. For example, the organisation may take an informed decision to keep the risk, in effect taking no action beyond identifying and evaluating the risk or opportunity.

Sub-clause 6.1.2 requires a planned approach with respect to these actions, with them initially being integrated into the quality management system prior to a subsequent evaluation to determine whether the action was effective in reducing the risk or realising the opportunity.

> Organisations are free to decide on the most appropriate risk management method to use.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This new requirement requires quality professionals to ensure that their organisations have robust risk management methodologies in place. These need to allow risks and opportunities relating to the QMS to be captured and assessed.

Depending on the outcome of this assessment, action then needs to be taken to mitigate the risk or to realise the opportunity. The standard requires the extent of this action to be proportionate to the risk or opportunity itself, ie major risks requiring major action(s).

Subsequently, organisations need to evaluate how effective the action that they took was.

Organisations are free to decide on the most appropriate risk management method to use.

This clause is related to several other clauses within the DIS with regards to its outcomes (ie what are the risks and opportunities for the organisation, and how are they to be addressed?). Consequently organisations truly need to understand it and apply it effectively. It is clear that wrong assessment will not result in a suitable quality management system, and hence not effective.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should ensure that the organisation is taking a planned approach to addressing risks and realising opportunities, and that any actions taken have been recorded. For those actions that have been completed, auditors should ensure that each action's effectiveness (or otherwise) has subsequently been assessed. They should also ensure that the action taken was proportionate to the risk or opportunity.

6.2 Quality objectives and planning to achieve them

6.2.1

▶ INTERPRETATION:

Sub-clause 6.2.1 is an enhancement and extension of ISO 9001:2008 requirements. It requires an organisation to set quality objectives for relevant functions, levels and processes within its quality management system. It is for the organisation itself to decide which functions, levels and processes are relevant.

The quality objectives must be consistent with the organisation's quality policy and be relevant to the conformity of products and services, and the enhancement of customer satisfaction.

Quality objectives must be measurable, take into account applicable customer and statutory and regulatory requirements, and be monitored in order to determine whether they are being met. They must also be communicated across the organisation and be updated as and when the need arises.

Information on the quality objectives needs to be retained by the organisation as documented information.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is an extension of ISO 9001:2008 sub-clause 5.4.1 "Quality objectives". The requirement for quality objectives to be measurable and consistent with the organisation's quality policy is carried across, as is the requirement for objectives to be set for relevant functions and levels.

New for DIS 9001:2014 are requirements to set quality objectives for applicable processes, to set objectives that are relevant to the enhancement of customer satisfaction, and to monitor progress against the achievement of objectives.

For organisations that simply created the minimum amount of quality objectives necessary to conform to the requirements of ISO 9001:2008, this clause will mean some additional work to demonstrate the value of the quality objectives at relevant functions, levels and processes within the organisation.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Additional requirements have been included in the DIS as set out above. Auditors should ensure that organisations are able to evidence that they are complying with these new requirements.

6.2.2

▶ INTERPRETATION:

Sub-clause 6.2.2 is an enhancement of ISO 9001:2008 sub-clause 5.4.2, which now clearly states requirements that were previously inferred within ISO 9001:2008.

The organisation must undertake planning in order to determine how its quality objectives will be achieved.

Sub-clause 6.2.2 requires an organisation to determine the work required in order to realise its quality objectives, the resources necessary to undertake this work, who will be responsible for ensuring that the work is done and when the work needs to be completed by.

Additionally, the organisation must determine how it will evaluate the work done to determine whether it has led to the objective being realised.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Sub-clause 6.2.2 focuses not just on what needs to be done, but also asks organisations to identify what resources will be required to do it, who will do it, when it will be completed and how it will be evaluated in order to determine if it has realised the objective.

The target set on completion of quality objectives means more robust monitoring of the objectives will need to take place.

It may be necessary for the organisation to revisit its existing quality objectives in order to ensure that the enhanced planning requirements of clause 6.2.2 have been applied.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should look for evidence that effective planning is taking place to support the achievement of the organisation's quality objectives. They should ensure that this takes into consideration the new requirements set out above.

6.3 Planning of changes

▶ INTERPRETATION:

Clause 6.3 is an enhancement of ISO 9001:2008 clause 5.4.2b. When the organisation determines there is a need to change the quality management system, clause 6.3.3 of DIS 9001:2014 requires such changes to be carried out in a controlled manner. Changes need to be planned first and then logically enacted. The organisation needs to be clear as to what it is attempting to achieve by implementing the proposed change and what the consequences (both positive and negative) of proceeding may be. It needs to assess whether the integrity of the quality management system could be compromised (or indeed improved) as a result of making the change. The organisation must also consider whether there are sufficient resources available to effect the change and whether any changes in responsibilities or authority levels are necessary to drive the change through.

The organisation is required to retain documented information relating to planned changes that impact its quality management system.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is an extension of ISO 9001:2008 sub-clause 5.4.2b, which requires the integrity of the quality management system to be preserved whenever changes to it are planned or implemented.

The new requirements in DIS 9001:2014 build on this, adding in specific considerations that an organisation must undertake when planning and implementing QMS changes.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should ensure that the organisation is able to evidence that it has taken into account the considerations detailed in DIS 9001:2014 clause 6.3 when planning and implementing changes to its quality management system.

7 SUPPORT

7.1 Resources

7.1.1 General

▶ INTERPRETATION:

Sub-clause 7.1.1 updates ISO 9001:2008 clause 6.1 "Provision of resources".

It requires an organisation initially to determine and then subsequently provide the resources necessary to establish, implement, maintain and continually improve its quality management system.

In doing so, the organisation is required to consider both the capabilities and constraints on its existing internal resources as well as what needs to be sourced from external providers.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The ISO 9001:2008 clause 6.1b reference to "identifying resources needed to enhance customer satisfaction" has been removed from sub-clause 7.1.1. (although this is still implied through 5.1.1 f).

There is now an explicit requirement to consider both internal and external QMS resource requirements.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors must now evidence that organisations have considered their need for external resources in addition to their need for internal ones.

7.1.2 People

▶ INTERPRETATION:

Sub-clause 7.1.2 requires an organisation to provide those people necessary for the effective operation of its quality management system and its processes in order that it can consistently meet customer and applicable statutory and regulatory requirements.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is essentially an existing requirement separated out from ISO 9001:2008 clause 6.1 "Provision of resources". Whereas the reference to meeting statutory and regulatory requirements was implicit in clause 6.1, it is now explicit.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach required.

7.1.3 Infrastructure

▶ INTERPRETATION:

Sub-clause 7.1.3 updates ISO 9001:2008 clause 6.3 "Infrastructure".

As is the case for ISO 9001:2008, the requirements for infrastructure in DIS 9001:2014 are centred around identifying, providing and maintaining the means to enable processes to operate effectively.

The examples of infrastructure appearing in the DIS are essentially the same as those in ISO 9001:2008, with some minor revisions to wording. "Buildings, workspace and associated utilities" becomes "buildings and associated utilities"; "process equipment (both hardware and software)" becomes "equipment including hardware and software"; and "supporting services (such as transport, communication or information systems)" becomes "transportation, and information and communication technology".

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

No action required.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No changes to audit approach required.

> An environment for the operation of processes can include physical, social, psychological, environmental and other factors.

7.1.4 Environment for the operation of processes

Sub-clause 7.1.4 updates ISO 9001:2008 clause 6.4 "Work environment".

▶ INTERPRETATION:

DIS 9001:2014 requires organisations to "determine, provide and maintain" a suitable environment for the operation of processes. This is a little more prescriptive than the ISO 9001:2008 wording, which simply required organisations to "determine and manage" their work environment.

The note gives examples of environments for the operation of processes. The examples include physical, social, psychological environmental and other factors, including temperature, cleanliness and others.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The key change here is that "work environment" now becomes "environment" necessary for the operation of processes reflecting an increased focus throughout the standard on a process-based approach.

As is the case for sub-clause 7.1.3 "Infrastructure" in DIS 9001:2014, the purpose of maintaining the process environment is to assure conformity of products and services.

The note to sub-clause 7.1.4 DIS 9001:2014 explains that an environment for the operation of processes can include physical, social, psychological, environmental and other factors, such as temperature, humidity, ergonomics and cleanliness.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors will need to audit the organisation's process environment, not its work environment. As well as physical factors, this now includes social and psychological factors too.

When auditing organisations currently operating to ISO 9001:2008, auditors will want to see evidence that the auditee organisation is applying this updated requirement to all processes determined necessary for the quality management system.

7.1.5 Monitoring and measuring resources

▶ INTERPRETATION:

Sub-clause 7.1.5 updates ISO 9001:2008 clause 7.6 "Control of monitoring and measuring equipment".

Where an organisation uses monitoring or measuring to demonstrate that its products and services conform to requirements, it must make sure that it provides the necessary resources to ensure that its monitoring and measuring results are valid.

These resources need to be suitable to the type of monitoring or measurement being undertaken and must be maintained in order to ensure they remain fit for purpose.

The organisation must maintain appropriate documented information as evidence that monitoring and measuring resources are fit for purpose.

In instances where measurement traceability has been identified as a requirement, a customer or relevant interested party expectation, or is considered by the organisation as essential in order to provide confidence in the measurement results, measuring instruments must be verified or calibrated against international or national measurement standards at specific intervals or prior to their use.

If no such standards exist, the organisation must record the basis it is using for calibrating or verifying the measuring instrument in the form of documented information.

Measuring instruments must be identified in such a way that their calibration status can be determined. They must also be protected to prevent them being adjusted, damaged or subjected to deterioration.

If measuring equipment is found to be defective, previous results need to be revisited and any necessary corrective action implemented.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

DIS 9001:2014 sub-clause 7.1.5 relates to monitoring and measuring "resources" whereas ISO 9001:2008 clause 7.6 is concerned solely with monitoring and measuring "equipment". This change is an acknowledgement that, in certain instances, humans also carry out monitoring or measurement activity without reliance on equipment, eg a chef releasing food to be served in a restaurant.

The organisation is now required to retain documented information as evidence that the measuring and monitoring resources are fit for purpose, not just the monitoring or measuring equipment (referred to as "instruments" in DIS 9001:2014).

If measurement traceability is required then measuring instruments are subject to additional controls. These are, however, just a reworking of those currently contained in ISO 9001:2008 clause 7.6 "Control of monitoring and measuring equipment".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note that where measurement traceability is required, measuring instruments are subject to additional controls. These are commensurate with the current requirements of ISO 9001:2008 clause 7.6.

If measurement traceability is not required then auditors must satisfy themselves that the monitoring and measuring resources an organisation has employed are suitable and fit for purpose, and that arrangements are in place to ensure their continued fitness for purpose.

Auditors should also ensure that documented information is being maintained by the organisation to demonstrate that monitoring and measuring resources are fit for purpose in these instances.

> If measuring equipment is found to be defective, previous results need to be revisited.

7.1.6 Organizational knowledge

This is a new requirement aimed at ensuring that organisations take steps to capture and preserve knowledge and learning, which is necessary for the effective operation of their processes and for ensuring the conformity of their products and services.

▶ INTERPRETATION:

This is a broad requirement directed primarily at ensuring the organisation has or obtains the knowledge resources necessary to respond to changing business environments referred to in clause 4.1, changing customer and interested party needs and expectations referred to in clause 4.2 and, where applicable, related improvement initiatives. As such, this requirement has strong links with management review activities.

This knowledge needs to be maintained and made available to the extent necessary. The organisation can choose how best to do this; there is no explicit requirement for organisational knowledge to be held as documented information.

The organisation must re-assess the extent of its organisational knowledge if it is considering making changes to its quality management systems in response to changing needs or trends in its operation environment.

If the current level of knowledge is deemed insufficient then the organisation must take steps to enhance it. This is an attempt to ensure that organisations make informed decisions in respect of updates to their quality management systems.

Note 1 identifies types of organisational knowledge while Note 2 identifies potential sources of organisational knowledge.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This is a new requirement. Quality professionals should ensure that they introduce processes to address the requirements above.

The notes to clause 7.1.6 give good examples of what "organisational knowledge" can include as well as to how additional knowledge can be obtained.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

This is a new requirement. Auditors should ensure that organisations have taken steps to identify the organisational knowledge necessary to establish the continuing conformity of their products and services.

Auditors should ensure that organisational knowledge has been communicated as necessary within the organisation and that it is being maintained and protected.

They should also ensure that an assessment of organisational knowledge has taken place prior to any changes made to the quality management system in response to changing needs or trends.

7.2 Competence

▶ INTERPRETATION:

Clause 7.2 is essentially an amalgamation of ISO 9001:2008 sub-clause 6.2.1 "Human Resources – General" and sub-clause 6.2.2 "Competence, training and awareness" (save for requirement 6.2.2d, which now transfers to DIS 9001:2014 clause 7.3 "Awareness").

The organisation must determine the competency requirements for those people performing work under its control. Once these competency requirements have been determined, the organisation must then ensure that those people possess the necessary competencies, either on the basis of their education, training or experience. The organisation is required to take action to acquire the necessary competence. Actions taken need to be evaluated for effectiveness.

The Note in this clause gives examples of applicable actions, such as training, recruitment or use of external people.

If those people are found not to be competent, action must be taken to make them competent or to gain the necessary competencies from other sources, for example, recruitment or use of external people. An assessment needs to be subsequently undertaken to determine whether this has been successful in raising competence to the required level.

Organisations must retain appropriate documented information to evidence the competence of its people.

Note: clause 7.2 refers to "People performing work under its control". This embraces contract and agency people, as well as people performing processes and functions that have been outsourced to external providers. These are operating under the control of the organisation, recognised in DIS 9001:2015 by a specific reference in clause 8.4.3 to the need to communicate to external providers' competence and qualification requirements as applicable. In practice this requirement is likely to be addressed through procurement processes.

IMPLICATIONS FOR QUALITY PROFESSIONALS:

Competence is defined as the "ability to apply knowledge and skills to achieve intended results". Competence now needs to be considered in terms of its potential impact on "quality performance", as opposed to "its ability to affect conformity to product requirements".

Organisations are still required to take action to address any competency issues and subsequently to check that this action has been effective. Additionally, organisations are still required to maintain evidence to demonstrate that people doing work under its control are competent. This evidence needs to be maintained as documented information.

While clause 6.2.2 of 9001:2008 requires records of education, training, skills, and experience, clause 7.2.5 DIS 9001:2014 requires documented information as evidence of competence.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No substantive change although attention is drawn to the related requirements for control of externally provided products and services within DIS 9001:2014 clause 8.4.1.

Also, some organisations' records regarding clause 6.2.2 may have to be reviewed to assess whether they can also constitute evidence of competence. If not, documented information of evidence of competence needs to be identified and established or maintained (eg a clean driving licence can be evidence of competence for a driver)

> Under ISO 9001:2008, the awareness requirement for personnel was quite limited.

7.3 Awareness

▶ INTERPRETATION:

Awareness has now been elevated from a constituent element of sub-clause 6.2.2 "Competency, training and awareness" in 9001:2008 to a separate sub-clause in its own right.

The requirements contained in the new clause 7.3 now apply to all "persons doing work under the organisation's control". This is more expansive than under ISO 9001:2008 where the organisation needed to ensure that "its personnel" were aware.

In respect of what individuals need to be aware of, this too has been extended. Under ISO 9001:2008, the awareness requirement for personnel was quite limited; necessitating only an awareness of the relevance and importance of the work they were conducting, and an appreciation as to how this contributed to the organisation's quality objectives.

Now, however, there are explicit requirements for people doing work under the organisation's control to be aware of the organisation's quality policy, any quality objectives that are relevant to them, how they are contributing to the effectiveness of the QMS and what the implications are of them not conforming to QMS requirements.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Clause 7.3 contains expanded requirements. Quality professionals should note that the people who need to be made aware now extends to all persons doing work on the organisation's behalf (previously this was limited to the organisation's personnel). Quality professionals should also note that additional information as set out above must be communicated to these individuals.
The important factor here is the addition of the requirement to make persons doing work under the organisation's control aware of the implications of not conforming to the QMS.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

DIS 9001:2014 has enhanced requirements for awareness both in terms of who needs to be made aware and also in terms of what they need to be made aware of. The latter is now detailed explicitly within this clause. Audit professionals must ensure that the organisation is able to provide evidence that these enhanced requirements are being met.

7.4 Communication

▶ INTERPRETATION:

This expands on the current ISO 9001:2008 sub-clause 5.5.3 by extending its scope to include external communications as well as internal ones.

> The new clause is more prescriptive in respect of the mechanics of the communication.

Clause 7.4 "Communication" encompasses all internal and external communication relating to an organisation's QMS. Each organisation must determine those QMS-related matters on which it wishes to communicate. Once this has been done, consideration must then be given as to the timing of such communications, their target audience and their method of delivery.

Note: reference to external communication in this clause does not encompass specific customer communication requirements of ISO 9001:2008 sub-clause 7.2.3, which are largely retained in DIS 9001:2014 sub-clause 8.2.1.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The new clause is more prescriptive in respect of the mechanics of the communication; sub-clause 5.5.3 refers to the need for "communication to take place" whereas DIS 9001:2014 clause 7.4 requires organisations to determine on what it will communicate, when it will communicate, with whom it will communicate and how it will communicate. Quality professionals should be prepared to evidence these considerations.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should ensure that organisations are identifying external communications as well as internal communications that need to take place in respect of the operation of its quality management system. They should also ensure that the organisation has determined what it needs to communicate, when it will communicate, with whom it will communicate and how it will communicate.

7.5 Documented information

7.5.1 General

▶ INTERPRETATION:

Sub-clause 7.5.1 confirms that an organisation's quality management system includes both documented information identified as required in DIS 9001:2014 and documented information identified by the organisation as necessary for the effective operation of its quality management system.

The note to the clause advises that the extent of documented information present can differ between organisations due to their size, complexity and the competency of their people.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

No change – these requirements are already contained in ISO 9001:2008 clause 4.2.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach is required.

7.5.2 Creation and updating

▶ INTERPRETATION:

When documented information is created or updated, the organisation must ensure that it is appropriately identified and described (eg title, date, author, reference number). It must be in an appropriate format (eg language, software version, graphics) and on appropriate media (eg paper, electronic).

Documented information must be reviewed and approved for suitability and adequacy.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

No further action is required as these requirements are already contained within the sub-clauses that comprise ISO 9001:2008 clause 4.2.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach is required.

7.5.3 Control of documented information

7.5.3.1

▶ INTERPRETATION:

The organisation is required to control documented information in order to ensure that it is available where needed and that it is suitable for use. It must also be adequately protected against improper use, loss of integrity and loss of confidentiality.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that, while the requirement for a documented procedure setting out how documents are to be controlled has been removed, the need to control documented information remains.

The requirements in sub-clause 7.5.3.1 mirror current requirements in ISO 9001:2008.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note that, while the requirement for a documented procedure specifying how documents are to be controlled has been removed, the requirements above are unchanged from ISO 9001:2008.

7.5.3.2

▶ INTERPRETATION:

The organisation must determine how it will distribute, access, retrieve and use documented information.

It must decide how it will store and preserve documented information, and how it will control any changes to the documented information. It must also decide its retention and disposal arrangements.

The organisation is also required to identify any documented information of external origin to the organisation that it considers necessary for the planning and operation of the organisation's quality management system. Such documentation must be identified and controlled.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

While ISO 9001:2008 contains requirements for controls in respect of the distribution and retrieval of documents, DIS 9001: 2014 extends these also to cover the "access" and "usage" of documented information required by the organisation's quality management system and by DIS 9001:2014.

Where organisations chose to hold their documented information in electronic forms, there may be a need to revisit access controls (passwords/logins) and authorisation levels in order to ensure current controls are appropriate. Organisations will need to consider how such systems are to be protected when passwords are lost and how access to the documented information can be preserved in the event of system unavailability. They will also be required to demonstrate how the integrity of their documented information is maintained.

The Note in clause 7.5.3.2 states access can imply "permission to view only", or "permission to view and authority to change".

With most organisations moving to electronic documents that are maintained and accessed remotely using passwords, etc. this can mean more controls that need to be demonstrated if claiming compliance.

▶ IMPLICATIONS FOR AUDIT

Auditors will increasingly find themselves having to access and use electronic systems in order to evidence how organisations are controlling their documented information. This could require a technical upskilling.

Auditors will need to establish, prior to commencing an audit, whether an electronic system is in place and will need to make the necessary arrangements with the organisation to ensure that they can access and use such systems.

8 OPERATION

8.1 Operational planning and control

▶ INTERPRETATION:

Clause 8.1 requires the organisation to plan, implement and control those processes that it has previously identified (see clause 4.4) as necessary in order for it to meet product or service requirements. It must additionally plan how it will address any risks and opportunities that may impact these processes and, therefore, its ability to achieve these requirements.

The planning process commences with the organisation establishing its product/service requirements. Once this has been completed, the organisation must then consider its processes and for each it must establish the criteria for the process, how it will control the process, the acceptance criteria for the outputs of each process and the resources necessary to support each process. This means that the inputs (triggers for the process), outputs (products and/or services), and resources and controls (to ensure that the required outputs are achieved) should be determined. In addition, what makes the output acceptable also needs to be determined – this can be targets, measures, values, KPIs, specifications and other criteria as relevant to the output.

Subsequently, the organisation is required to create and keep documented information to the extent it determines is necessary to allow it to ensure that its processes are being carried out as planned, and that the products and services that are being produced conform to the identified requirements and acceptance criteria.

The extent of planning for the provision of products and services must be proportionate to the size, nature and complexity of the organisation's operations.

The output from operational planning and control must be suitable for the organisation's operation.

The organisation must control planned changes to the provision of product and services, and must review the consequences of any unintended changes. Where necessary, the organisation should take action to address or mitigate any adverse effects.

Any outsourced processes must be controlled in accordance with clause 8.4 "Control of externally provided products and services".

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The requirement to plan and develop processes is not new. For DIS 9001:2014, however, this has been extended also to include "implementation and control".

The term "product realization" has been withdrawn and replaced by "operation", and the requirement for "Planning of product realization" has been replaced by "Operational planning and control".

The ISO 9001:2008 clause 7.1a requirement to determine quality objectives for products or services has been relocated to DIS 9001:2014 sub-clause 6.2.1, which calls for quality objectives to be established at relevant functions, levels and processes.

ISO 9001:2008 clause 7.1b refers to providing "resources specific to the product". DIS 9001:2014 refers to "resources needed to achieve conformity to product and service requirements".

The requirement for planning proportionate to the organisation's size, nature and complexity comes straight across from ISO 9001:2008, as does the requirement for the output from operational planning and control to be in a form that is suitable for use by the organisation.

The new control-focused requirements centre on ensuring that processes are implemented as planned, including actions to address risks and opportunities. This needs to be evidenced by means of documented information.

"The output from operational planning and control must be suitable for the organisation's operation."

> Auditors also need to evidence that processes have been implemented and controlled as planned.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

This section should be read in conjunction with guidance given to audit professionals under clause 4.4. The increased focus on the process approach makes properly understanding clause 4.4 and clause 8.1 a fundamental requirement for auditors.

Audit professionals should note that this clause now includes implementation and control requirements, not just planning and development requirements as per ISO 9001:2008. They should also note the change of terminology – "Product realization" has been replaced by "Production and service provision".

Clause 4.4, together with clause 8.1, makes it very clear that the organisation is required to determine and plan (design) its processes to meet requirements. As such, auditors need to evidence that this has been done, ie evidence that the process (including process inputs, outputs, resources, controls, criteria, process measurement and performance indicators) has been planned. The fact that they exist is not in itself evidence that they have been planned.

There is also a clear link and, hence, audit trail, from clause 6.1 "Actions to address risks and opportunities" through to clause 8.1. For those risks and opportunities that the organisation has determined need to be addressed, auditors should gather evidence that these actions have been integrated into the management system; as such, these actions should be verifiable at process level – for example, evidence of controls, acceptance criteria and resources to address the risks and opportunities.

Auditors also need to evidence that processes have been implemented and controlled as planned, and in so far as they relate to process planning and control, evidence that the organisation has evaluated the effectiveness of actions taken to address risks and opportunities.

Auditors should also gather and evaluate evidence relating to planned changes and to any unintended changes.

8.2 Determination of requirements for products and services

8.2.1 Customer communication

Sub-clause 8.2.1 requires an organisation to ensure that it has processes in place to allow it to communicate with its customers on matters relating to its products and services, enquiries, contracts or order handling (including amendments); customer views and perceptions (including customer complaints), the handling or treatment of customer property if applicable; and specific requirements for contingency actions when relevant.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that these requirements are essentially the same as for ISO 9001:2008 sub-clause 7.2.3 "Customer communication", but with the addition of new requirements to communicate in respect of the handling or treatment of customer property and specific requirements for contingency actions where relevant. The ISO 9001:2008 requirement to obtain "customer feedback" has been amended to obtain "customer views and perceptions".

A change here that may have implications for quality practitioners is that the clause on customer communication now appears before the determination and reviewing of requirements. This is to demonstrate the importance of communicating with the customer on understanding the requirements before determining what the organisation intends to offer them.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the changes and additional requirements set out above.

8.2.2 Determination of requirements related to the products and services

▶ INTERPRETATION:

The organisation is required to put in place a process to ensure that requirements for the products and services it intends to offer to customers have been defined. This includes the capture of any applicable statutory and regulatory requirements.

Once this has been done, the organisation must then ensure that it has the ability to meet the defined requirements and substantiate the claims it is making for the products and services it intends to supply.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This replaces ISO 9001:2008 sub-clause 7.2.1. The new clause represents a subtle change in emphasis in the nature of the interaction between supplier and customer in respect of determining customer requirements. In ISO 9001:2008, the organisation determines customer requirements before reviewing these and then proceeding to design or develop a product or service. DIS 9001:2014 starts from the position that the organisation has already determined the products and services it intends to offer to customers, taking into account customer requirements. This reflects the way that much of business takes place these days, with organisations effectively setting out their product portfolios from which customers must choose.

Quality professionals should note the new requirement to establish, implement and maintain a process that ensures that the organisation has determined the requirements for the products and services it intends to offer to customers.

An organisation will need to be able to substantiate any claims it makes about its products or services in respect of them meeting defined requirements.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the requirement for a process that ensures that the organisation has determined the requirements for the products and services it intends to offer to customers. They should seek evidence that this is in place.

Auditors should also evidence that the organisation is able to substantiate any claims it is making for the products and services it offers.

8.2.3 Review of requirements related to products and services

▶ INTERPRETATION:

The organisation is required to review requirements relating to its products and services.

This review needs to consider requirements set by the customer, including ones relating to delivery and post-delivery. It must also include consideration of any requirements not expressly stated by the customer but that are known to be necessary for the product or service to be suitable for the customer's intended use.

In addition, the review must consider any statutory or regulatory requirements relating to the product or service, and any new or changed requirements that differ from those previously determined.

Requirement reviews must take place before the organisation commits to supply products or services to a customer and, should it be necessary, must seek to resolve any differences between what was originally ordered or contracted and what the organisation has now determined the requirements to be.

If the customer does not provide a documented statement of their requirements then the organisation must confirm the customer's requirements with the customer prior to the order/ contract being accepted.

Documented information relating to requirement reviews must be retained by the organisation. Where requirements have been revised as a result of review, this must be identified in the documented information.

Where product or service requirements have been changed, the organisation must ensure that any relevant documents are amended and that relevant personnel are made aware of the changed requirements.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that this sub-clause amalgamates ISO 9001:2008 sub-clauses 7.2.1 and 7.2.2.

There is no substantive change to content, though there is recognition that when reviewing requirements relating to products or services, these requirements could now include those arising from relevant interested parties – not just from customers.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Audit professionals should ensure that requirements from relevant interested parties are considered as part of an organisation's product and service requirement review process.

8.3 Design and development of products and services

8.3.1 General

▶ INTERPRETATION:

In those instances where the organisation has not established detailed requirements for products or services, or where these have not been defined by the customer or other interested parties to the extent that they are adequate to allow production or service provision to take place, the organisation must implement and maintain a design and development process.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Sub-clause 8.3.1 is a new clause that mandates the introduction of a design and development process in the circumstances set out above.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Audit professionals should ensure that a design and development process exists and is being operated in the circumstances set out above.

Increased knowledge of the products and services, and methods of arriving at them, will be required by auditors in order to be able to verify whether the organisation's QMS should or should not include design and development.

8.3.2 Design and development planning

▶ INTERPRETATION:

The organisation is required to plan and control the design and development of its products and services.

The design and development process will comprise a number of stages, each of which will be subject to controls.

When determining the stages and controls to be applied to its design and development process, the organisation must consider:

- the complexity, nature and duration of the design and development activities;
- that any requirements that specify particular process stages must be included, for example design and development reviews;
- the design and development verification and validation that is required at each stage;
- the responsibilities and authorities of those involved in the design and development process;
- the need to ensure that the interfaces between individuals and parties involved in the design and development process are appropriately managed;
- whether it is necessary to involve the customer and/or user groups in the design and development process;
- the documented information that will be necessary to confirm the design and development requirements have been met.

> Increased knowledge of the products and services, and methods of arriving at them, will be required by auditors.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

DIS 9001:2014 sub-clause 8.3.2 builds on the existing ISO 9001:2008 sub-clause 7.3.1 "Design and development planning".

Sub-clause 8.3.2 is more explicit than its predecessor in terms of what needs to be taken into consideration when planning the design and development process. However, it is likely that organisations complying with ISO 9001:2008 will already be undertaking these activities anyway. This could be, for example, by involving the customer and/or user groups in the design and development process where appropriate, and in ensuring that the organisation's design and development process takes into account any identified requirement to include specific stages, such as design or a development review.

The requirement to retain documented information that confirms that the design and development requirements have been met is a new addition to this clause.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Audit professionals should ensure that organisations are able to evidence that they have taken into consideration the explicitly referenced considerations relating to the design and development process set out above.

They should also ensure that the organisation has retained documented information to confirm that its identified design and development requirements have been met.

8.3.3 Design and development inputs

▶ INTERPRETATION:

DIS 9001:2014 sub-clause 8.3.3 requires the organisation to determine specific inputs into its design and development process.

These include:

- any requirements that are essential for the specific type of product or service that is being designed and developed (including any functional or performance-related requirements as applicable);
- any applicable statutory or regulatory requirements;
- any codes of practice that the organisation has agreed to implement;
- any resource needs, whether internal and external, required for the design and development of the product or service;

> The organisation must ensure that design and development inputs are adequate, complete and unambiguous.

- the potential consequences of failure due to the nature of the product or service;
- the customer's and other interested parties expected level of control of the design and development process.

The organisation must ensure that design and development inputs are adequate, complete and unambiguous. If there are any conflicts between design inputs, then these must be resolved.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

These are amended requirements. This sub-clause builds on the previous requirements of ISO 9001:2008 sub-clause 7.3.2 "Design and development inputs".

The ISO 9001:2008 requirements to include as a design and development input information from previous similar designs has been deleted. In its place are new requirements to include as a design and development input "internal and external resource needs" and "the potential consequences of design or development failure" based on the nature of the product or service.

The remaining ISO 9001:2008 design and development input requirements are essentially unchanged.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors need to verify that the organisation has addressed the specific new requirements set out in DIS 9001:2014 sub-clause 8.3.3 – specifically, those relating to resource requirement and the consequences of design or development failure.

8.3.4 Design and development controls

▶ INTERPRETATION:

The organisation is required to apply controls to its design and development process in order to ensure that:

- the results from undertaking the design and development process are clearly defined;
- design and development reviews take place in accordance with planned arrangements;
- the design and development outputs meet the design and development inputs (verification);
- the resulting products and services are fit for their intended use or specified application where this is known to the organisation (validation).

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This sub-clause draws in a number of existing requirements from ISO 9001:2008 sub-clauses 7.3.3, 7.3.4, 7.3.5 and 7.3.6.

There are no new requirements.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach is required.

8.3.5 Design and development outputs

▶ INTERPRETATION:

The organisation must ensure that the outputs from design and development meet the input requirements for design and development, and are suitable for use in subsequent processes.

As applicable, design outputs must include or reference any related monitoring or measuring requirements and acceptance criteria.

Finally, the organisation must ensure that the products that are to be produced or the services that are to be delivered are fit for their intended purpose and are safe to use.

The organisation is required to retain documented information resulting from the design and development process.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that this sub-clause corresponds to ISO 9001:2008 sub-clause 7.3.3 "Design and development outputs".

It is essentially unchanged, except that the requirement to "include or reference monitoring and measuring requirements" has been added to ISO 9001:2008 sub-clause 7.3.3c.

A requirement to retain documented information resulting from the design and development process has also been added into this sub-clause.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the additional requirement for documented information in respect of sub-clause 8.3.5.

They should also note the need for design outputs to reference monitoring and measuring requirements as applicable.

8.3.6 Design and development changes

▶ INTERPRETATION:

If changes are made to either design inputs or design outputs, then the organisation must review, control and identify these in order to ensure that conformity to requirements is maintained.

The requirement to review and exercise control applies at all stages during the development of products or services and, subsequently, for example, after the product or service has been delivered.

The organisation is required to retain documentary information relating to design and development changes.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This sub-clause is essentially unchanged from ISO 9001:2008 sub-clause 7.3.7 "Control of design and development changes".

The order of "review" and "identify" has been reversed in DIS 9001:2014, with review taking place first. "Control" has been added.

The ISO 9001:2008 requirement to "review, verify, validate and, as appropriate, approve design changes before implementation" is no longer explicitly defined but is implied in the wording of sub-clause 8.3.6.

There are further implications for quality professionals of organisations that are significantly affected by the new requirement for "post-delivery activities" in sub-clause 8.5.5.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change to the current audit approach.

8.4 Control of externally provided products and services

8.4.1 General

▶ INTERPRETATION:

The organisation must ensure that externally provided processes, products or services meet the organisation's specified requirements.

The organisation must employ controls to enable it to verify that externally provided processes, products or services meet these requirements.

These controls must be put into effect when the organisation is seeking to obtain:

- products and services from the external providers for incorporation into the organisation's own products and services;
- products and services to be provided directly to the customer by the external provider on the organisation's behalf;
- outsourced processes or parts of processes from an external provider.

The organisation must determine and put in place criteria that allow it to evaluate and select external providers, and that allow it subsequently to monitor their performance.

Criteria relating to the re-evaluation of external providers also need to be established and implemented.

Documented information needs to be retained evidencing the results of external provider evaluations, re-evaluations and the monitoring of their performance.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The implications of this sub-clause are broadly in line with the requirements of ISO 9001:2008 sub-clauses 7.4.1 and 7.4.3; however, DIS 9001:2014 sub-clause 8.4.1 now explicitly sets out those instances in which the organisation must apply controls to external providers (see the bullet points above).

The new requirement here is to establish criteria to monitor the performance of external providers and to have the results of the evaluation, re-evaluation and performance as documented information.

In ISO 9001:2008 sub-clause 7.4.1, it is required to keep records of the "criteria" for selection, evaluation and re-evaluation of the suppliers. Whereas, in DIS 9001:2014, organisations are required to record not only the criteria, but also the results of these activities, including performance. This has many implications for quality practitioners. If previously the organisation has not maintained records of the "results" of these activities, now they need to do so, meaning more documented information than before.

Note: an "external provider" is a provider external to the scope of the quality management system. As such, if a scope of registration covers a single plant in a wider group structure then anything sourced from other members of the group would be "externally provided" and hence subject to the requirements of clause 8.4.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the new requirement for the organisation to establish criteria to allow it additionally to monitor the performance of external providers. This must be maintained as documented information.

They should also note the requirement for organisations to provide a record of the results of their monitoring of the external provider's performance as documented information.

8.4.2 Type and extent of control of external provision

▶ INTERPRETATION:

The organisation must determine the type and extent of controls that it wishes to apply to external providers.

In deciding the nature and extent of these controls, the organisation needs to take into consideration the potential impact that the externally provided processes, products or services could have on its ability to supply conforming products and services to its customers. The organisation must also consider how effective it considers the controls that are being applied by the provider are.

The organisation must establish and carry out checks in order to ensure that externally provided processes, products and services do not detrimentally affect its ability consistently to deliver conforming products and services to its customers.

If processes have been outsourced to an external provider, the same considerations as set out above must be applied when determining the extent of controls to be applied.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This clause brings in elements from ISO 9001:2008 sub-clauses 7.4.1 "Purchasing process" and 7.4.3 "Verification of purchased product".

In ISO 9001:2008 sub-clause 7.4.1, when determining the nature and extent of controls to be employed to suppliers, the organisation needed to consider "the effect of the purchased product on subsequent product realization or the final product". However, in DIS 9001:2014 this has been amended to "the potential impact of the externally provided processes, products or services on the organisation's ability consistently to meet customer and applicable statutory and regulatory requirements".

The requirement to verify externally provided processes, products or services remains in sub-clause 8.4.2. However, in ISO 9001:2008 the verification was to ensure "the purchased product met specified purchase requirements". In DIS 9001:2014, the verification is to ensure "the externally provided processes, products and services do not adversely affect the organisation's ability to deliver conforming products and services to its customers".

> The requirement to verify externally provided processes, products or services remains in sub-clause 8.4.2

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the revised requirements as set out above, including those relating to outsourced processes.

8.4.3 Information for external providers

▶ INTERPRETATION:

Sub-clause 8.4.3 sets out the information that the organisation is required to communicate to external providers of processes, products and services.

This information must include applicable requirements for the following:

- Requirements relating to the products or services to be provided or the processes to be performed by the external provider on behalf of the organisation.
- Requirements relating to the approval or release of the product or service, methods, processes or equipment.
- Requirements relating to the competency of personnel, including any necessary qualifications they must possess.
- Any actions that the external provider must undertake in order to ensure that it interacts appropriately with the organisation's quality management system.
- Details as to how the external provider's performance will be monitored and controlled by the organisation.
- Details of any verification activities that the organisation (or its customer) intends to perform at the external provider's premises.

The organisation is required to ensure that the requirements it intends to communicate to the external provider are reviewed for adequacy prior to their being communicated.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

DIS 9001:2014 sub-clause 8.4.3 draws in existing requirements from ISO 9001:2008 sub-clauses 7.4.1 "Purchasing processes", 7.4.2 "Purchasing information" and 7.4.3 "Verification of purchased product".

Essentially, these requirements are unchanged. There is an acknowledgement that organisations may need to communicate not just the products or services they wish to receive, but also any processes they want the external provider to undertake on their behalf.

The requirement for the organisation to communicate, as applicable, the necessary qualification of personnel has been expanded to cover the competency and qualification of personnel.

The requirement for the organisation to communicate any "quality management system requirements", as applicable, has been expanded to "their (ie the external provider's) interactions with the organisation's quality management system".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach is required.

8.5 Production and service provision

8.5.1 Control of production and service provision

▶ INTERPRETATION:

Sub-clause 8.5.1 requires organisations to control the way in which they provide their products and services.

These controlled conditions must include, as appropriate, ensuring that:

- documented information that defines the characteristics of the product or service is available;
- documented information that defines the activities that need to be performed to produce the product or deliver the service is available, and that this specifies the results that are to be achieved;
- monitoring and measurement takes place at appropriate points in the production process to ensure that both the processes themselves and the process outputs meet the organisation's acceptance criteria;
- the process environment and infrastructure are suitable;
- suitable monitoring and measurement resources are made available;
- personnel are competent and, where necessary, appropriately qualified;
- for processes where the results cannot be verified by subsequent monitoring or measurement, the process itself is initially validated and then periodically re-evaluated;
- product and service release, delivery and post-delivery activities are implemented.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This sub-clause is an amalgamation and expansion of ISO 9001:2008 sub-clauses 7.5.1 "Control of production and service provision" and 7.5.2 "Validation of processes from production and service provision".

The reference to "work instructions" has been replaced by a reference to "documented information that defines the activities to be performed and the results achieved".

"The results achieved" is an important addition; these may not appear in existing documentation describing the activities to be performed or in records generated from them.

There is now an explicit requirement to ensure monitoring and measurement activities are undertaken at appropriate points. This is in order to verify processes are being controlled and that process outputs, products and services are meeting their acceptance criteria. This is an expansion on ISO 9001:2008 sub-clause 7.5.1e.

The "use of suitable equipment" has been replaced by the "use and control of suitable infrastructure and process environment".

Reference is made to monitoring and measuring "resources" as opposed to "monitoring and measuring equipment", reflecting the fact that monitoring may be being carried out by humans.

The ISO 9001:2008 sub-clause 7.5.2b reference to the "qualification of personnel" has modified to "the competency and, where applicable, required qualification of persons emphasising competency over qualification".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the changed requirements as set out above.

> Sub-clause 8.5.1 requires organisations to control the way in which they provide their products and services.

8.5.2 Identification and traceability

▶ INTERPRETATION:

The organisation is required to put arrangements in place to allow its process outputs to be identified where this is necessary, in order for it to be able to demonstrate that they conform to requirements.

The organisation must be able to identify the status of process outputs in respect of any monitoring and measurement requirements it has set, at all stages of production or service provision.

In cases where traceability is a requirement, the organisation must additionally ensure that its process outputs are uniquely identifiable. Documented information that enables product outputs to be traced back through the quality management system must be retained.

The note to the sub-clause reminds us that process outputs can include, but are not limited to, products, services, intermediate parts or components.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Essentially, this sub-clause is unchanged from ISO 9001:2008 sub-clause 7.5.3 "Identification and traceability".

DIS 9001:2014 sub-clause 8.5.2 states that identification and traceability is to be employed "where necessary to ensure the conformity of products and services". However, ISO 9001:2008 simply states that it is to be employed "where appropriate".

There are terminology changes. DIS 9001:2014 refers to "process outputs", the "provision of products and services" and "documented information", whereas ISO 9001:2008 refers to "products", "product realization" and "records". However, the substance of the requirements is identical.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change in audit approach is necessary.

8.5.3 Property belonging to customers or external providers

▶ INTERPRETATION:

Sub-clause 8.5.3 requires the organisation to take care of property that has been supplied to it for incorporation into its products or services by customers or by external providers.

The organisation must ensure that any such property is identified, verified, protected and safeguarded.

> If the property is incorrectly used, lost or damaged, the organisation must make sure that this is reported back to the customer.

If the property is incorrectly used, lost or damaged, the organisation must make sure that this is reported back to the customer or external provider.

A note provides examples of the types of property that this clause is intended to cover.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This requirement is essentially unchanged from ISO 9001:2008 sub-clause 7.5.4. However, it has now been extended to cover not just customer property, but also property belonging to the external providers that has been provided to the organisation for use or incorporation into the products and services. As such, existing arrangements must be revised to reflect this.

For organisations that use external providers' property, this can impact on their QMS in relation to gaps in controls needed, and, hence, there are implications for the quality practitioners of such organisations to ensure compliance with this requirement.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Evidence is required to confirm that the controls appearing in ISO 9001:2008 relating to customer property have been extended to cover property from external providers.

8.5.4 Preservation

▶ INTERPRETATION:

Sub-clause 8.5.4 requires the organisation to take appropriate measures during production and service provision to safeguard process outputs, in order to maintain their conformity to requirements.

The note to sub-clause 8.5.4 provides examples of "preservation". These include identification, handling, packaging, storage, transmission or transportation and protection.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Notwithstanding that this sub-clause refers to "process outputs" as opposed to "product", its requirements are essentially the same as for ISO 9001:2008 sub-clause 7.5.5 "Preservation of product".

Examples of what preservation could include (eg identification, handling, packaging, storage and protection) now appear in a note to sub-clause 8.5.4 instead of in the body of the sub-clause itself.

"Transportation" and "Transmission" have been added to the original ISO 9001:2008 preservation examples. The implications for quality professionals of this addition means that if their organisation's products are data and information, they will need to look at the risks of loss of data and security issues during transmission (eg website subscriptions, web-based information, data attached to emails, information in emails). This is something that previously might have not been considered a "quality issue".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No substantive change to current audit practice.

8.5.5 Post-delivery activities

▶ INTERPRETATION:

Sub-clause 8.5.5 requires the organisation to determine the nature and extent of any post-delivery activities it needs to undertake.

When making this decision, the organisation must consider the risks associated with the particular product or service, the nature of the product or service, how the product or service will be used and what the product or service's intended lifetime is.

In addition, consideration of any post-delivery activities also needs to take into account customer feedback and any applicable statutory or legal requirements.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should be aware that these are new requirements. They should ensure that their quality management system is amended to address this clause. They should also note the necessary considerations relating to risk, the nature of the product or service, its intended lifetime, customer feedback and applicable statutory or legal requirements.

This can potentially require some work for the quality practitioners if the organisation's products or services are of high risk and have a large or indefinite lifetime (eg medical devices, aerospace, research results or test results).

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should be aware that these are new requirements. They should ensure that the organisation has taken into account the necessary considerations when determining the nature and extent of post-delivery activities.

8.5.6 Control of changes

▶ INTERPRETATION:

The organisation is required to control any unplanned changes that are considered essential in order to ensure that products or services continue to meet their specified requirements.

In such instances, the organisation must retain documented information describing the results of the review of the changes, the person(s) authorising the changes and any necessary actions

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should be aware that this is a new clause. If the organisation determines that it must make unplanned changes to its processes in order to ensure its products or services continue to conform to their specified requirements, then these changes must be made in a controlled manner. There are several implications for quality practitioners of organisations that are regularly making unplanned changes as a result of market or customer needs, or lack of supplier performance.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should evidence that the organisation has controlled unplanned changes in accordance with the requirements set out above.

8.6 Release of products and services

▶ INTERPRETATION:

Clause 8.6 requires the organisation to carry out predetermined verification at appropriate points in the production/delivery process in order to verify that products and services meet agreed acceptance criteria. Evidence that the product or service meets the acceptance criteria needs to be retained.

Products or services must not normally be released to the customer until all of the planned tests and checks have been satisfactorily completed, unless someone with the relevant authority agrees to their early release. Where applicable, permission for early release must also be obtained from the customer.

Documented information that allows the individual authorising any early releases to be identified must be retained.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Sub-clause 8.6 refers to "products and services" instead of "products", and to the need to retain "documented information" as opposed to "evidence" of conformity to requirements. Apart from this, it is otherwise equivalent to ISO 9001:2008 sub-clause 8.2.4.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No substantive change. Auditors should note the refreshed terminology – "products and services" replaces "products", and "documented information" replaces "record".

8.7 Control of nonconforming process outputs, products and services

▶ INTERPRETATION:

The organisation is required to identify any process outputs, products or services that do not conform to their intended requirements. Controls need to be established and implemented to ensure that these "nonconforming" process outputs, products or services are not delivered to the customer or used unintentionally.

Where nonconforming process outputs, products or services are identified, the organisation is required to take action to correct the fault. This corrective action must be proportionate, reflecting both the nature of the nonconformity and its ability to impact the organisation's intended product or service. This requirement also applies to nonconforming products or services that are identified after delivery to the customer.

The organisation is required to deal with nonconforming process outputs, products or services in one or more of the following ways:

- by correcting the fault;
- by segregation or containment of the process output, product or service;
- by securing the process output, product or service's return;
- by suspension of the provision of products and services;
- by informing the customer;
- by obtaining authorisation to use the process output, product or service "as is";
- by obtaining authorisation to release the product or service;
- by obtaining authorisation to re-provide the product or service;
- by obtaining authorisation for acceptance under a concession.

If the organisation decides to correct a nonconforming process output, product or service then it must verify that the corrective action it has taken has restored the process output, product or service's conformity to requirements.

The organisation is required to retain documented information of actions taken where nonconforming process outputs, products or services have been identified. This needs to include details of any concessions obtained and details of the person or authority that made decisions in respect of dealing with the nonconformity.

> Where nonconforming process outputs, products or services are identified, the organisation is required to take action to correct the fault.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This clause contains minor changes in requirements from ISO 9001:2008 clause 8.3 "Control of nonconforming product".

DIS 9001:2014 includes reference to "process outputs" and "services" as well as to products.

There is no longer a requirement for a documented procedure that defines the controls and related responsibilities and authorities for dealing with nonconforming products.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the removal of the requirement for a documented procedure covering control of nonconforming products.

The documented information requirement equates to the existing ISO 9001:2008 requirement to retain records of nonconformities and resultant actions.

9 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

▶ INTERPRETATION:

Sub-clause 9.1.1 requires the organisation initially to determine what it needs to monitor and measure. Once this has been done it must then decide how it is going to carry out these activities in order to ensure that the results obtained are valid. The requirement for methods to ensure valid results also extends to the organisation's analysis and evaluation activities. In addition, the organisation must also determine when monitoring and measurement should be carried out and at what stage the results of monitoring and measurement should be analysed and evaluated.

Organisations are subsequently required to ensure that monitoring and measurement takes place in accordance with the requirements the organisation has set itself. They must ensure that where monitoring and measurement takes place, documented information is retained to evidence the results.

Finally, there is a requirement for organisations to evaluate the quality performance and effectiveness of their quality management systems.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The decision on whether to monitor or to measure, and what to monitor and measure, can have a significant impact on the effectiveness of the QMS, its implementation and its results. Inevitably the decision will be based on:

- the degree of confidence that the organisation has in the operational controls that it has established for its processes, and their effectiveness (this can use historical data on performance to establish what should be monitored and what should be measured)
- the degree of confidence that the organisation needs to have in the operational controls that it has established for its processes, and their effectiveness (this can use the output from the organisation's approach to addressing risks and opportunities; as well as the needs and expectations of its customers and interested parties)

Inevitably, in the absence of data for either of the above points, the organisation may have to have a comprehensive set of monitoring and measurement activities until such time that it can build enough information and/or data to help inform its decision making for future monitoring and measurement activities. An example is where certification bodies carry out more frequent surveillance visits of those organisations newly certified, and once confidence is achieved through these visits and their results, they can reduce the frequency of future surveillance visits. Ultimately, this is all about risk assessment.

> The organisation must also determine when monitoring and measurement should be carried out.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note the additional requirement for organisations to evidence evaluation of the results of monitoring and measurement, not just their analysis.

They should confirm that the organisation has considered what, how and when to measure and that the outcomes from this decision result are ensuring appropriate process control.

They should also note a new requirement to monitor the quality performance and effectiveness of the organisation's quality management system.

9.1.2 Customer satisfaction

▶ INTERPRETATION:

Sub-clause 9.1.2 requires the organisation to put in place arrangements to monitor the degree to which customers believe their requirements for products and services have been met.

Additionally, there is also a requirement for the organisation to obtain data relating to customer perceptions of the organisation itself, as well as the products and services it provides.
The organisation needs to identify how this information is to be secured and the way in which it is to be used.

Guidance is provided by means of the Note similar to that in 9001:2008 clause 8.2.1 as to the methods that could be employed to obtain customer views.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This clause supersedes ISO 9001:2008 sub-clause 8.2.1.

The principal change here is that consideration of customer perception now includes soliciting perceptions of the organisation and of its products and services, and not just perceptions as to whether the organisation has met the customer's requirements. The organisation must also decide how it is going to obtain and use customer satisfaction information.

> It is to be used to evaluate the performance of processes and of external providers.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should ensure that the organisation has met the additional requirements to seek customer perception about the organisation itself and also its products and services. They should also ensure that the organisation has identified how it intends to obtain customer satisfaction information.

9.1.3 Analysis and evaluation

▶ INTERPRETATION:

Sub-clause 9.1.3 requires the organisation to analyse and evaluate appropriate data and information that it has obtained either internally or externally for a variety of pre-defined purposes.

These include: to demonstrate that the organisation's products and services conform to requirements; to assess and enhance customer satisfaction; to ensure the conformity and effectiveness of the quality management system; and to demonstrate that planning has been successfully implemented. Additionally, it is to be used to evaluate the performance of processes and of external providers, and to determine the need or opportunity for improvements within the quality management system.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Sub-clause 9.1.3 now refers to analysis "and evaluation" of data, rather than just "analysis" as in ISO 9001:2008 clause 8.4.

Quality professionals should note the new requirement for data and information to demonstrate that planning has been effective.

The ISO 9001:2008 clause 8.4c reference to preventive action has been removed.

Sub-clause 9.1.3 refers to evaluating the performance of processes, whereas ISO 9001:2008 refers to providing information relating to the characteristic and trends of processes.

The ISO 9001:2008 clause 8.1 reference to "statistical techniques and the extent of their use" has been removed.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should note that organisations now need to evidence both analysis and evaluation of data and information. It is not sufficient just to carry out an analysis without interpreting the results.

They should ensure that organisations are able to evidence through analysis and evaluation that planning has been effective.

Note the requirement to evaluate the performance of processes.

Note the removal of references to preventive action and statistical techniques.

9.2 Internal audit

9.2.1

▶ INTERPRETATION:

Sub-clause 9.2.1 confirms the requirement for the organisation to carry out internal audits at planned intervals in order to determine whether the quality management system conforms to both the organisation's own requirements and the requirements of ISO 9001.

Internal audits must also identify whether the quality management system is being effectively implemented and maintained.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that these requirements are essentially unchanged from ISO 9001:2008 sub-clause 8.2.2.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

No change to current audit practice.

9.2.2

▶ INTERPRETATION:

Sub-clause 9.2.2 sets out a series of requirements relating to how audit programmes must be structured, what audits must cover, who should undertake audits and how audits are to be reported.

When designing an audit programme, organisations need to consider their quality objectives, the importance of the processes concerned, customer feedback, changes within the organisation, risks and opportunities, and the results of previous audits.

Each audit needs to have a defined scope and its own audit criteria.

Audits and auditors need to be impartial and objective.

Finally, the findings from audits need to be fed back to the relevant management with any required corrections or corrective actions being taken in a timely manner.

Documented information needs to be retained to provide evidence that the audit programme has been implemented. Documentary information must also exist to provide evidence of the results of audits.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

There is no longer a requirement for organisations to establish a documented internal audit procedure. However, organisations may still chose to operate one if they so wish.

Quality professionals should note the need to retain documented information evidencing the implementation of an audit programme and also the results of audits.

They should also note that when designing the internal audit programme, customer feedback, organisational changes, and quality objectives now need to be considered explicitly.

Note that the results of the audits should be reported to the relevant management versus 9001:2008 where the "nonconformities are reported to the management of the area audited".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should not necessarily expect to find a documented internal audit procedure in place. However, they must be able to access documented information confirming the implementation of an audit programme by the organisation. Documented information must also be available to evidence the results of audits.

When determining how the audit programme has been designed, auditors should ensure that customer feedback, organisational changes, and risks and opportunities have been brought into consideration.

> The initial requirement is to revisit the status of any actions identified at previous reviews.

9.3 Management review

9.3.1

▶ INTERPRETATION:

Sub-clause 9.3.1 requires reviews of the quality management system to be undertaken by top management at planned intervals in order to ensure the quality management system's continuing suitability, adequacy and effectiveness. This is essentially unchanged from the existing ISO 9001:2008 sub-clause 5.6.1.

However, DIS 9001:2014 requires management reviews additionally to consider any changes to the context of the organisation and also the degree of alignment between the quality management system and the strategic direction of the organisation.

Sub-clause 9.3.1 details the items that top management must (as a minimum) consider during a management review.

The initial requirement is to revisit the status of any actions identified at previous reviews. The next requirement calls for consideration of the organisation's context, including both internal and external issues that are relevant to the QMS and its strategic direction.

The third requirement is for consideration of quality performance. Here, specific reference is made to the need for trends and indicators relating to nonconformities and corrective action, monitoring and measurement results, audit results and customer satisfaction, process performance and conformity of products and services. Also contained within the quality performance section is a requirement to consider issues concerning external providers and other interested parties, as well as the adequacy of resources.

Finally, management reviews must consider opportunities for improvement and the status of risks and opportunities.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

This sub-clause supersedes ISO 9008:2008 sub-clause 5.6.2 "Review input". While the overall purpose of management reviews remains unchanged, there are now new "strategic" items relating to context, risk and opportunities to be included on the agenda. In addition, there is a requirement that "trends and indicators" be used to monitor specific elements of quality performance. This contrasts with ISO 9001:2008, where the requirement is simply to "include information" on these items.

The implication for organisations is a more comprehensive review process. It should be noted that a lot of the information listed will already be available in some organisations, but may not have been addressed under 'quality management' in the past.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should expect to evidence a more strategicallyfocused management review. Context, risks and opportunities need to be considered, as well as the alignment of the quality management system to the organisation's overall strategic objectives. Auditors should also note the explicit requirement for organisations to use "trends and indicators" to monitor the performance of their quality management systems.

9.3.2

▶ INTERPRETATION:

Sub-clause 9.3.2 sets out specific requirements in respect of the outputs from management reviews.

These must include decisions as to whether there is a need to change any aspect of the quality management system including, but not limited to, the level of resources provided to support the operation of the QMS, as well as any decisions relating to continual improvement opportunities.

The organisation must retain documented information to provide evidence as to the results of management reviews.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note that this sub-clause supersedes ISO 9001:2008 sub-clause 5.6.3 "Review output". The requirements of both sub-clauses are, however, essentially the same.

Organisations are now, however, required to retain documented information as evidence of the results of the management reviews (rather than records of management review as stated in 9001:2008).

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should expect to evidence the same outputs from management reviews as at present. However, they should note that the results of management reviews can now be held in any format that the organisation chooses.

10 IMPROVEMENT

10.1 General

▶ INTERPRETATION:

Clause 10.1 is a new clause. It sets out the headline requirement for organisations actively to seek out and realise improvement opportunities that will better enable the organisation to meet customer requirements and enhance their customers' satisfaction.

When looking to improve, organisations should review their processes, seek to improve their products and services, and seek to improve their quality management system results.

The associated note reminds us that improvement does not always take place on a continual basis. Sometimes it occurs as a result of corrective action, sometimes through innovation and sometimes as a result of re-organisation.

Preventive action no longer exists as a concept in DIS 9001:2014 – all references to it have been removed. Instead, it has been replaced by risk-based thinking.

Also, the explicit requirement to improve the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data and corrective actions, and management review that appears in ISO 9001:2008 sub-clause 8.5.1 "Continual improvement" has been removed from DIS 9001:2014.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

Quality professionals should note the new requirements. Organisations should ensure that they have systems in place to review their processes, products and services, and the performance of their quality management system as a whole, with the objective of making improvements.

Note: there are no longer any requirements to be fulfilled relating to preventive action (previously ISO 9001:2008 sub-clause 8.5.3). As a result, it is no longer necessary to have a documented procedure for preventive action.

Pay attention to improving products and services not only to meet known requirements, but also the "predicted requirements".

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should continue to seek objective evidence that improvement is taking place. They should note, however, that while improvement does not need to be continual, it does need to be evidenced as occurring.

Auditors should look for evidence that the organisation is considering improvement in respect of its processes, products and services, and the performance of the quality management system overall. In the case of products and services, this is to meet not just known but predicted requirements.

They should note that there is no longer a requirement to audit preventive action as a distinct entity.

Auditors should also note the removal of the explicit requirement for the organisation to improve its quality management system through the review of the quality policy, quality objectives, audit results, analysis of data and corrective actions, and management review.

10.2 Nonconformity and corrective action

10.2.1

▶ INTERPRETATION:

Sub-clause 10.2.1 sets out how the organisation is required to act when nonconformity is identified.

In such instances, the organisation is required to take whatever action is necessary to control and correct the nonconformity, and to deal with any resultant consequences.

Once this has been completed, the organisation can then move on to consider whether any further action is required to prevent a similar nonconformity occurring at some point in the future. This requires the organisation to determine what caused the nonconformities and then to consider whether the potential for a similar problem remains.

The organisation is then required to implement any actions identified as needed, review their effectiveness and make changes to the quality management system if necessary.

This clause also recognises that the actions organisations take on nonconformities should be appropriate to the effect of those nonconformities.

The associated note recognises that there may be instances where it is impossible to eliminate the root cause of nonconformity altogether. Therefore in some instances, the best that may be possible is to reduce the likelihood of a similar occurrence happening again to an acceptable level.

The title of this sub-clause has changed – it was previously ISO 9001:2008 sub-clause 8.5.2 "Corrective action".

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

On discovering nonconformity, there is now an explicit requirement for organisations to determine whether other similar nonconformities actually do or potentially could exist.

There is also a requirement for the organisation to determine whether changes are required to the wider QMS in order to prevent a reoccurrence.

The note recognises that for certain circumstances it may be impossible to eliminate the cause of a nonconformity.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should evidence that, where nonconformities have been identified by an organisation, an investigation has been conducted to determine whether other similar nonconformities actually do or potentially could exist.

They should also evidence that where a nonconformity has occurred, the organisation has considered whether it needs to make changes to the wider system to prevent a reoccurrence.

10.2.2

▶ INTERPRETATION:

Sub-clause 10.2.2 requires the organisation to keep documented information detailing the nature of any nonconformity identified and the action that the organisation decided to take to address it. This documented information must also record the results of the corrective action.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The ISO 9001:2008 sub-clause 8.5.2 requirement for a documented corrective action procedure has been removed. Instead, the organisation is now required to retain "documented information".

If organisations wish to retain their existing documented corrective action procedure, then providing it meets the requirements of sub-clause 10.2.2, it will be accepted as documented information. Please note that the documented information will require the nature of the nonconformities to be recorded as well as any subsequent actions taken. This was not an explicit requirement of 9001:2008 sub clause 8.5.2. and is a new requirement.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should no longer expect to find a documented corrective action procedure. The organisation may elect to provide evidence that it is fulfilling the requirements of this sub-clause by other means, eg by the use of computer-based records.

Note the new requirement regarding the recording of the nature of nonconformities as well as subsequent action to be taken. Auditors should ensure that the organisation is meeting this additional requirement.

> Auditors should no longer expect to find a documented corrective action procedure.

10.3 Continual improvement

▶ INTERPRETATION:

Clause 10.3 requires the organisation to work continually to improve its quality management system in terms of its suitability, adequacy and effectiveness.

As part of the continual improvement process, the organisation is specifically required to use the outputs from analysis and evaluation (see sub-clause 9.1.3) and from management review (see clause 9.3) to determine areas of underperformance and to identify any opportunities for improvement.

Tools and methodologies should be employed as appropriate by the organisation to investigate the cause of underperformance and to support continual improvement.

▶ IMPLICATIONS FOR QUALITY PROFESSIONALS:

The ISO 9001:2008 sub-clause 8.5.1 requirement continually to improve the effectiveness of the QMS – specifically through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review – has been dropped.

Organisations will now need to demonstrate that they are using the outputs from their analysis and evaluation processes to identify areas of underperformance and opportunities for improvement. Appropriate tools and methodologies should be employed by the organisation to support this activity.

▶ IMPLICATIONS FOR AUDIT PROFESSIONALS:

Auditors should evidence that organisations are using the outputs from their analysis, evaluation and management review processes to identify improvement opportunities and quality management system underperformance. They should also verify that the organisation is using suitable tools and methodologies to support its investigation.

Annexes

Annex A (Informative) – Clarification of new structure, terminology and concepts

ISO 9001:2008 contained a single informative annex (Annex A). Within this was a table that mapped each ISO 9001:2008 clause to its ISO 14001:2004 (Environmental Management System Standard) counterpart.

There is no such table in DIS 9001:2014 Annex A, which instead introduces the new Annex SL-based structure that underpins the standard as well as the core concepts on which it is built. These include "Context of the organisation" as well as a "risk-based approach".

The method by which exclusions are handled also appears here. DIS 9001:2014 contains no reference to exclusions and the default position is that organisations are expected to meet all of the requirements of the standard unless it is impossible for them to do so. There is no option to "opt out" of specific requirements that an organisation may simply be uncomfortable with.

An explanation is provided in respect of "documented information". This term replaces "documented procedure" and "records", and has been incorporated throughout DIS 9001:2014 to align with other international standards. There is now much more freedom for organisations themselves to determine the nature and extent of their document holdings.

Organisational knowledge is a new requirement (sub-clause 7.1.5). Organisations are now required to determine and maintain the knowledge they possess, which is critical in respect of ensuring their products and services conform to requirements. This includes not just knowledge held in documents or on IT systems, but also in people's heads.

The final concept addressed is control of externally provided products and services. This supersedes ISO 9001:2008 clause 7.4 "Purchasing" and covers any "external" provision where external is external to the scope of the management system. This could be a traditional third-party supplier or another organisation in the same group or company if that organisation is not covered by the same scope as the purchasing organisation.

Annex B (Informative) – Quality management principles

This contains reworked quality management principles drawn across from ISO 9004:2009 "Managing for the sustained success of an organisation – A quality management approach".

The principles form the basis for all quality management system standards developed by ISO/ Technical Committee 176 including, but not limited to, the 9000 series. The seven principles contained in DIS 9001:2014 are: customer focus; leadership; engagement of people ("involvement of people" in ISO 9004:2009); process approach; improvement ("continual improvement" in ISO 9004:2009); evidence-based decision making ("factual approach to decision making" in ISO 9004:2009); and relationship management ("mutually beneficial supplier relationships" in ISO 9004:2009).

The 9004:2009 principle 'systems approach to management' has been deleted.

Each principle has an associated statement that provides an expanded description of the principle and an associated rationale that highlights the benefits an organisation should expect to realise should they adopt the principle.

Annex C Information – The ISO portfolio of quality management standards

Annex C provides details of the ISO 10000 series of quality management standards as well as ISO 19011, which relates to management system audits.

The ISO reference and title of each standard is given, as well as a short summary of what each standard is about.

Table C.1 cross-references each 10000 series standard to one or more specific clause(s) of DIS 9001:2014. 9000, 9004 and 19011 are similarly cross-referenced to DIS 9001:2014.

Updates

ISO 9001:2015 remains very much 'work in progress' and it is inevitable that the contents of the standard will change between now and its eventual date of issue. As a result, the analysis contained within this report is also subject to change.

The CQI and IRCA are committed to providing those who have purchased this report with updates free of charge when such changes occur. This will ensure that your initial investment in this document is protected.

Conclusion

When ISO 9001:2015 is published in the autumn of next year, it will signal the start of a three-year transition period during which those organisations wishing to move to the new version of the standard will need to make changes to their existing quality management systems.

The extent of work involved will very much depend on each organisation's starting point. Those who have embraced both the substance and the spirit of the 2008 version will have respectively less work compared to those who are simply meeting the base requirements at present.

Irrespective of the starting position, the migration process should begin now. ISO's data shows a significant dip in 9001 registrations immediately following the last major revision in the year 2000. While it is unclear exactly why this was the case, at least some of the reduction has been attributed to organisations leaving it too late to align their systems to the 2000 requirements, and, as a consequence, their certificates were withdrawn. For organisations that rely on 9001 certification to demonstrate their competency as a supplier, the loss of such certification will invariably have a direct impact on profitability. By starting now you can ensure you effect your transition in a controlled and timely manner well ahead of the September 2018 deadline.

> Irrespective of the starting position, the migration process should begin now.

Quality practitioners should start by familiarising themselves with the revised requirements as set out in this report and should then prepare plans to modify their existing quality management systems as necessary. Top management need to understand their new obligations and must be prepared to evidence leadership (as opposed to management) of their QMSs. Finally, both internal and external auditors will need to upskill, to equip themselves to assess a standard where old friends such as the management representative, the quality manual and procedures have disappeared and where new evidence sources have been introduced in their place.

The CQI and IRCA recognise that the proposed changes may seem a little daunting. That is why we have committed to running a series of roadshows, webinars, technical articles and briefings aimed at supporting our members, not just through these initial stages, but right through until the new standard is published. Whatever your role in the quality profession and whatever sector your organisation may operate in, the CQI and IRCA will be on hand to provide informed and impartial advice to facilitate your transition.

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